

EXHIBIT 13



Date: November 20, 2009

To: File

From: Cheryl Hastings

Subject: K062426, DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

The 510(k) submission for the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners includes prototype engineering prints for part numbers 1218-87-350, -456, -458, -460, -462, -464 and -466.

The prototype prints included in the 510(k) were compared to the Revision A production prints in Agile. No differences were noted in material specifications, diameters, spherical radii, surface roughness, angles, screw hole diameters, taper angles, or taper heights.

PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

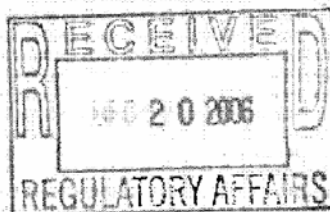
DEFENDANT
EXHIBIT
D-433

DEPUY022771622



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Kathy Harris
Director of Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

DEC 16 2006

Re: K062426

Trade/Device Name: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component prosthesis

Regulatory Class: Class III

Product Code: KWA

Dated: December 1, 2006

Received: December 4, 2006

Dear Ms. Harris:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

Page 2 - Ms. Kathy Harris

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Dec 15 06 10:32a

p. 4

Indications for Use

510(k) Number (if known): K062426Device Name: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use XX

(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number

K062426

DEC. 15. 2006 3:31PM

FDA-CDRH-ODE-POS

NO. 0899 P. 1/3



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DePuy Orthopaedics Inc.
% Ms. Kathy Harris
Director of Regulatory Affairs
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

DEC 15 2006

Re: K062426

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FDA-CDRH-ODE-POS

NO. 0899 P. 2/3

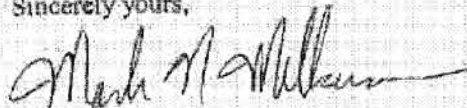
Page 2 - Ms. Kathy Harris

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEC. 15. 2006 3:31PM

FDA-CDRH-ODE-POS

NO. 0899

P. 3/3

Indications for Use

510(k) Number (if known): K062426Device Name: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

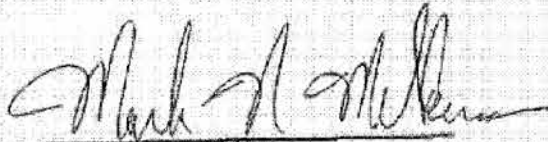
The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number

K062426



Special 510(k): Device Modification

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

(Modification to DePuy 36mm Pinnacle Metal-On-Metal
Acetabular Cup Liners, K003523)

700 Orthopaedic Drive Warsaw, IN 46580

Form Approved: OMB No. 0970-511 Expiration Date: August 31, 2005 See Instructions for OMB Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: MD6627007-956733 Write the Payment Identification number on your check.	
A completed Cover Sheet must accompany each original application or supplement subject to fees. The following actions must be taken to properly submit your application and fee payment:			
1. Electronically submit the completed Cover Sheet to the Food and Drug Administration (FDA) before payment is sent. 2. Include printed copy of this completed Cover Sheet with a check made payable to the Food and Drug Administration. Remember that the Payment Identification Number must be written on the check. 3. Mail Check and Cover Sheet to the US Bank Lock Box, FDA Account, P.O. Box 956733, St. Louis, MO 63195-6733. (Note: In no case should payment be submitted with the application.) 4. If you prefer to send a check by a courier, the courier may deliver the check and Cover Sheet to: US Bank, Attn: Government Lockbox 956733, 1005 Convention Plaza, St. Louis, MO 63101. (Note: This address is for courier delivery only. Contact the US Bank at 314-416-4821 if you have any questions concerning courier delivery.) 5. For Wire Transfer Payment Procedures, please refer to the MDUFMA Fee Payment Instructions at the following URL: http://www.fda.gov/cdrh/mdufma/faqs.html#3a . You are responsible for paying all fees associated with wire transfer. 6. Include a copy of the complete Cover Sheet in volume one of the application when submitting to the FDA at either the CBER or CDRH Document Mail Center.			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) DEPUY ORTHOPAEDICS INC 700 Orthopaedic Drive Warsaw IN 46582 US		2. CONTACT NAME Rhonda Myer 2.1 E-MAIL ADDRESS rmyer7@dpyus.inj.com 2.2 TELEPHONE NUMBER (include Area code) 574-371-4927 2.3 FACSIMILE (FAX) NUMBER (Include Area code) 574-371-4987	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) 352109957			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/dc/mdufma)			
Select an application type: <input checked="" type="checkbox"/> Premarket notification(510(k)), except for third party <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR)		3.1 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)	
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.			
<input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates, parents, and partner firms <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		<input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially	
6. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
7. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (FOR FISCAL YEAR 2005) \$3,833.00			

Form FDA 3601 (08/2003)

Close Window

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DePuy Orthopaedics, Inc.

PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA

Tel: +1 (574) 267 8143

August 17, 2006

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Reference: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Dear Madam/Sir:

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate for the DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners, as a **Special 510(k): Device Modification**. The modifications to the existing Pinnacle Metal-On-Metal Acetabular Cup Liners (K003523) are the addition of 2 larger size liners (40 and 44mm ID) and a the addition of a 36mm liner with a decreased outer diameter of 50mm. **The indications for the device remain the same as those cleared in the predicate 510(k) submissions.**

DePuy believes that this modification is eligible for the Special 510(k) process since the product has the same fundamental scientific technology and intended use as the predicate device.

Pursuant to 21 CFR 807.95(b), DePuy considers this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me at (574) 372-7098 or by e-mail at aschuler@dpus.jnj.com.

Sincerely,

Anne M. Schuler
Senior Regulatory Affairs Associate
DePuy Orthopaedics, Inc.

0000002

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0000003

Indications for Use

510(k) Number (if known): _____

Device Name: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *promusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 807 Subpart C)


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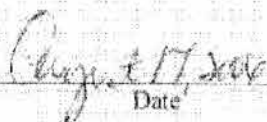
Concurrence of CDRH, Office of Device Evaluation (ODE)

0000004

Truthful and Accuracy Statement

In accordance with 21 CFR §807.87 (j), I believe, to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate and that no material fact has been omitted.


Sr Regulatory Affairs Associate


Date

0000005

Special 510(k)

Declaration of Conformity with Design Controls

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Verification
Activities

To the best of my knowledge, the verification activities, as required by the risk analysis, for the modification were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met.

Rebecca Nofz
Project Engineer, Hips
DePuy Orthopaedics, Inc.

Date

Manufacturing
Facility

The manufacturing facility, DePuy Orthopaedics, Inc., is in conformance with the design control requirements as specified in 21 CFR 820.30 and the records are available for review.

Edmund Frazee
Quality Assurance Engineer
DePuy Orthopaedics, Inc.

Date

0000006

SUMMARY OF SAFETY AND EFFECTIVENESS

NAME OF FIRM: DePuy Orthopaedics, Inc.
P.O. Box 988
700 Orthopaedic Drive
Warsaw, IN 46581-0988

510(k) CONTACT: Anne M. Schuler
Sr. Regulatory Affairs Associate

DATE PREPARED: August 17, 2006

TRADE NAME: DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

COMMON NAME: Acetabular Cup Liner

CLASSIFICATION: Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis (per 21 CFR 888.3330), Class III Device

DEVICE PRODUCT CODE: 87 KWA

SUBSTANTIALLY EQUIVALENT DEVICE(S): DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners (K003523, cleared December 13, 2000)

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners (K002883, cleared October 13, 2000)

DePuy ASR Modular Acetabular Cup System (K040627, cleared August 5, 2005)

DEVICE INFORMATION:**A. DEVICE DESCRIPTION**

The Pinnacle Metal-On-Metal (MOM) Acetabular Cup Liner is a metal liner that is intended for use with Pinnacle Acetabular Shells that have been cleared previously. The liners currently are offered with inner diameters (ID) of 28-36mm, this modification is to add 40 and 44mm IDs and to add a 36mm liner with a outer diameter (OD) of 50mm. The liners are offered in a neutral style only. The subject Pinnacle MOM liner is mechanically locked with the shell via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners and articulates with previously cleared M-Spec metal prosthetic femoral heads.

B. INTENDED USE AND INDICATIONS**Intended Use**

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

0000007

Indications

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuyPinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

C. BASIS OF SUBSTANTIAL EQUIVALENCE:

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that fall within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

0000008

**PREMARKET NOTIFICATION
CLASS III CERTIFICATION AND SUMMARY
(As Required by 21 CFR 807.94)**

I certify that, in my capacity as Sr. Regulatory Affairs Associate at DePuy Orthopaedics, Inc., a Johnson & Johnson company that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for metal-on-metal total hip systems. I further certify that I am aware of the types of problems to which metal-on-metal total hip systems are susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems is complete and accurate.

Anne M. Schuler

Anne M. Schuler

August 17, 2016

Date

K062426

(Premarket Notification [510(k)] Number)

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

0000009

SUMMARY OF THE TYPES AND CAUSES OF SAFETY OR EFFECTIVENESS PROBLEMS

METAL-ON-METAL TOTAL HIP SYSTEMS

Based on the literature summary provided in G960262 for the DePuy Ultima Metal-On-Metal Acetabular Cup System, the most significant complications associated with historical metal-on-metal total hip replacement systems include:

- Loosening, possibly related to surgical technique, poor fixation, sub-optimal bearing design resulting in high frictional torque and/or bearing seizure, or sub-optimal range of motion in early designs;
- Pain, possibly related to loosening;
- Calcar resorption, possibly related to poor early stem designs and not the metal-on-metal articulation;

Other potential complications which could be associated with metal-on-metal hip replacement, but have not been conclusively documented clinically include:

- Local and systemic reactions to increased metal ion release and metal wear debris, especially a higher incidence of certain site specific cancers;
- Fretting and corrosion of the implant due to galvanic corrosion between dissimilar metals;

Other types of safety and effectiveness problems which are associated with metal-on-metal hip replacement are those which are associated with all total joint replacements. These include: infection, dislocation, cardiovascular disorders (including venous thrombosis, pulmonary embolism, and myocardial infarction), pneumonia, atelectasis, hematoma, nerve damage, delayed wound healing, reaction to bone cement, metal sensitivity, bone fracture, soft tissue imbalance, failure to relieve pain, failure to restore range of motion and deformity of the joint.

In order to reduce the chance of complications with a metal-on-metal hip replacement device, the following conditions, which tend to adversely affect safety and/or effectiveness of any total joint arthroplasty, should be reduced or eliminated: marked osteoporosis with poor bone stock and danger of impaired abutment of implants, systemic and metabolic disorders leading to progressive deterioration of solid bone support for the implant (e.g. cortisone therapies, immunosuppressive therapies), history of general infectious disease (e.g. erysipelas) or local infectious disease, severe deformities leading to impaired anchorage or improper positioning of the implant, tumors of the supporting bone structure, allergic reactions to the implant materials, and tissue reactions to corrosion or wear products.

0000010

Special 510(k):
PINNACLE METAL-ON-METAL ACETABULAR CUP LINERS

Section I

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act and in accordance with subpart E of Part 807 of Title 21 of the Code of Federal Regulations and the Safe Medical Devices Act of 1990; DePuy Orthopaedics Inc., P.O. Box 988, Warsaw IN, 46581-0988, hereby submits the following information as a premarket notification for the Pinnacle Metal-on-Metal Acetabular Cup Liners.

I. ADMINISTRATIVE INFORMATION

A. MANUFACTURER AND SPONSOR OF THE 510(k) SUBMISSION

DePuy Orthopaedics, Inc.
P.O. Box 988
Warsaw, IN 46581-0988
Establishment Registration Number: 1818910

B. CONTACT PERSON

Anne M. Schuler
Sr. Regulatory Affairs Associate
DePuy Orthopaedics, Inc.
(574) 372-7098
FAX (574) 371-4987

II. DEVICE IDENTIFICATION

A. PROPRIETARY NAME

DePuy Pinnacle Metal-On-Metal Acetabular Cup Liner

B. COMMON NAME

Acetabular Cup Liner

C. CLASSIFICATION NAME AND REFERENCE

CFR 888.3330 Hip joint metal/metal semi-constrained with an uncemented acetabular component prosthesis, Class III Device

D. DEVICE PRODUCT CODES

87 KWA

III. COMPLIANCE WITH SPECIAL CONTROLS

Sections 513 and 514 of the Act, as amended under the Safe Medical Devices Act of 1990, do apply to this type of device, but a performance standard has not yet been promulgated. Further, DePuy is not aware of any requirements for postmarket surveillance or other special controls for this device at this time.

0000011

IV. STERILITY AND PACKAGING

The subject devices are supplied packaged and sterilized by exposure to Cobalt-60 Gamma Radiation at a minimum dose of 25 kilogray.

- The sterilization method has been validated by using by ANSI/AAMI/ISO 11137, *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization*.
- The Sterility Assurance Level (SAL) is set at 10^{-6} .
- No claims are made regarding pyrogenicity.

The package materials protecting sterility are HCW 2773-coated TYVEK® lid stock and KODAR® PETG Copolyester 6763 blisters.

V. PREDICATE DEVICE INFORMATION

The predicate devices for this submission are:

- DePuy Pinnacle 36mm Metal-On-Metal Acetabular Cup Liners cleared in K003523, December 13, 2000
- DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners cleared in K002883, October 13, 2000
- DePuy ASR Modular Acetabular Cup System cleared in K040627 August 5, 2005

VI. INDICATIONS FOR USE

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

These are the **same indications for use** that were previously cleared for the Pinnacle MOM Acetabular Cup Liners in K003523 and K002883.

VII. INTENDED USE

The subject Pinnacle Metal-On-Metal Liners are intended to be used with the DePuy Pinnacle metal acetabular shells to resurface the acetabular socket in cementless total hip arthroplasty.

0000012

VIII. LABELING AND INSTRUCTIONS FOR USE

Representative draft labels and draft Instructions for Use (IFU) are provided in Exhibit IV.

The IFU is the same as the one currently used with both the Pinnacle 28mm and 36mm inner diameter MOM Acetabular Shell components. The only changes made to the Instructions for Use are editorial changes to allow the use of 40 and 44mm femoral heads with the 40 and 44mm acetabular liners. No changes have been made to the Indications, Contraindications, Warnings, Precautions, or Adverse Effects.

IX. ENGINEERING DRAWINGS AND PART NUMBERS

Engineering drawings are provided in Exhibit II. Part numbers are provided in Exhibit I.

0000013

Special 510(k)
Section II

DEVICE DESCRIPTION

The Pinnacle Metal-On-Metal Acetabular Cup Liner is part of a modular system designed to replace the natural articular surface of the hip joint in total hip replacement. The acetabular component is provided as two separate units, a previously cleared porous coated hemispherical outer shell manufactured from titanium alloy (Ti-6Al-4V) and a liner manufactured from wrought Co-Cr-Mo metal alloy, which locks into the outer shell via a taper junction. The liner component articulates with a metal femoral head of an appropriate diameter.

The current Pinnacle Metal-On-Metal Liners are offered with inner diameters (ID) of 28 and 36mm. The 28mm liners have an outer diameter (OD) range of 48-66mm and the 36mm liners have an OD range of 52-66mm. Both are offered in a neutral style only. The 28mm liners were cleared in K002883 and the 36mm liners cleared in K003523. The subject liners are geometrically identical to the previously cleared 28 and 36mm liners with the following modifications:

- Increased ID to 40mm with an OD range of 56-60mm
- Increased ID to 44mm with an OD range of 62-66mm
- Decreased OD of 36 mm liner to 50mm

The larger ID size subject liners fall within the range of sizes cleared in the DePuy ASR Modular Acetabular Cup System (K040627). The ASR System consists of a one-piece metal acetabular cup which mates with a metal femoral head. There are no separate liners to this system as the liners are integral to the one piece acetabular cups. The ID range of metal cups cleared for this system is 38.6 – 54.6 mm.

The 40 and 44mm subject liners are designed to fit DePuy Pinnacle metal acetabular shells with an OD range of 56-66mm. The 36mm subject liner is to be used with the 50mm Pinnacle metal acetabular shells. They are locked into the shells via a taper junction which is identical to the taper junction used for the cleared 28 and 36mm liners. The 40 and 44 mm liners are intended for use with DePuy 40 and 44 mm M-Spec Co-Cr-Mo femoral heads previously cleared for use with 40 and 44mm polyethylene liners in K060031. The 36 mm liner is intended for use with the 36 mm Co-Cr-Mo heads cleared for use with metal liners in K003523. A list of compatible components is provided in Exhibit III.

Representative photographs of the subject liners are shown in figures 1 and 2.

0000014

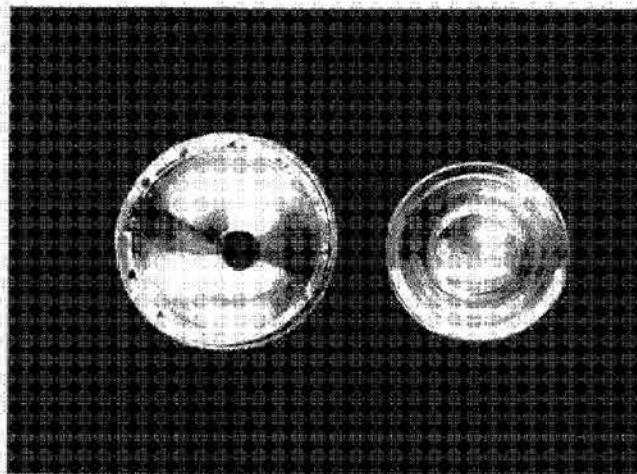


Fig. 1 Pinnacle Acetabular Shell (left) and Metal-On-Metal Liner (right)

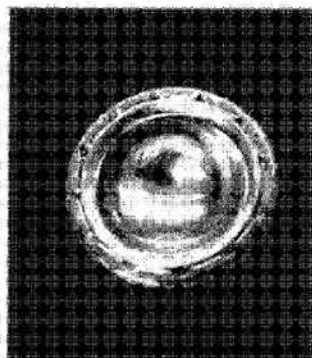


Fig. 2 Pinnacle Acetabular Shell and Metal-On-Metal Liner, Assembled

In metal-on-metal hip implants the clearance between the head and liner interface is critical to ensure that the bearing surfaces receive adequate lubrication for wear reduction. It is known that in modern metal-on-metal hip implants a fluid film lubrication may occur where a thin microscopic layer of lubricant completely separates the head and cup liner bearing surfaces thus protecting the articulating surfaces during relative motion. By protecting these surfaces, the fluid film lubrication plays a role in reducing the wear of metal-on-metal bearings. The diametrical clearances for the subject liners with compatible femoral head are the same as those for similar size components of the ASR system and the 36 mm Pinnacle metal liner (See Table 1). Therefore, it is expected that the fluid film lubricant layer produced with the subject liners will be the same as that for the previously cleared ASR Modular Acetabular Cup System (K040627) and the 36mm Pinnacle metal liner (K003523) indicating the subject liners will have similar wear rates. This has been confirmed through an in-vitro hip simulator wear test. The report for this study is provided in Exhibit VI.

0000015

**Table 1: DIAMETRICAL CLEARANCES FOR SUBJECT
DEVICES AND PREVIOUSLY CLEARED DEVICES**

Clearance (microns)	Pinnacle 40mm	Pinnacle 44mm	Pinnacle 36mm (K003523)	ASR 39mm (K040627)	ASR 41mm (K040627)	ASR 43mm (K040627)	ASR 45mm (K040627)
Min	80	80	80	80	80	80	80
Max	120	120	120	120	120	120	120

0000016

Special 510(k)

Section III

DIFFERENCES AND SIMILARITIES:

The similarities and differences between the DePuy and the predicate devices are listed in Table 2.

0000017

Table 2. Similarities and Differences Between the Subject and Predicate Devices

Characteristics	Subject Device	Predicate Device #1	Predicate Device #2	Predicate Device #3
Device Name	DePuy Pinnacle Metal Acetabular Cup Liner	DePuy Pinnacle 36 mm Metal Acetabular Cup Liner (K003523)	DePuy Pinnacle 28mm Metal Acetabular Cup Liner (K002883)	DePuy ASR Modular Acetabular Cup System (K040627)
Material	Wrought Co-Cr-Mo Alloy	Wrought Co-Cr-Mo Alloy	Wrought Co-Cr-Mo Alloy	Cast Co-Cr-Mo Alloy
Design	Separate liner which locks into metal acetabular shell, Neutral Style only	Separate liner which locks into metal acetabular shell Neutral Style only	Separate liner which locks into metal acetabular shell Neutral Style only	One piece metal acetabular cup, no separate liner
Locking Mechanism	Taper Lock	Taper Lock	Taper Lock	N/A
Intended Use	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty	Total Hip Arthroplasty
Sizes (mm): Inner Diameter (ID) Outer Diameter (OD)	ID = 36,40,44 OD = 50,56,58,60,62,64, 66	ID = 36 OD = 52,54,56,58,60,62,64, 66	ID = 28 OD = 48,50,52,54,56,58,60,62, 64,66,68	ID = 38,40,42,44,46,48,50,52,54,56,58, 60,62
Sterilization	Gamma	Gamma	Gamma	Gamma
Packaging	<ul style="list-style-type: none"> HCW 2773-coated TYVEK® lid stock KODAR® PETG Copolyester 6763 blisters 	<ul style="list-style-type: none"> HCW 2773-coated TYVEK® lid stock KODAR® PETG Copolyester 6763 blisters 	<ul style="list-style-type: none"> HCW 2773-coated TYVEK® lid stock KODAR® PETG Copolyester 6763 blisters 	<ul style="list-style-type: none"> HCW 2773-coated TYVEK® lid stock KODAR® PETG Copolyester 6763 blisters

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Special 510(k)

Section IV

SUMMARY OF DESIGN CONTROL ACTIVITIES:

The Design verification activities conducted for the Pinnacle Metal-On-Metal Acetabular Liners were performed based on the possible failure modes of the device. Table 2 lists the modifications that were made to the device, the associated risks from the changes, verification activities performed to evaluate the risks, acceptance criteria and a summary of the results of the testing.

0000019

Table 2. Device Modifications, Risks, & Design Control Activities

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
Increased liner Diameter of liner to 40 and 44 mm	1. Effect on wear properties	In-vitro Hip Simulator Wear study - non-clinical study to evaluate the wear performance of the liners. The study was conducted on a hip-joint simulator for 6 million cycles using four subject 44mm liners with 44mm M-Spec heads (test group) and four predicate 28mm liners with 28mm heads (control group). The head/liner interface was lubricated with bovine serum. Wear was determined by measuring the weight loss every half million cycles.	The subject liners must have wear properties equal to or better than those of the predicate liner.	The total average wear over 6 million cycles was $0.56 \pm 0.12 \text{ mm}^3$ for the 28mm liners and $0.11 \pm 0.02 \text{ mm}^3$ for the 44mm liner. The wear rates during the break-in period were $0.85 \pm 0.48 \text{ mm}^3$ for the 28mm liners and $0.07 \pm 0.02 \text{ mm}^3$ for the 44 mm liner. The results demonstrate a 92% wear reduction during the break-in period and a 80% wear reduction overall with the subject 44 mm liner as compared to the predicate 28mm liner. The requirements of the test were met. A complete test report is provided in Exhibit V.
		Diametrical Clearance of the MOM interface is critical to wear performance, therefore diametrical clearances of head/liner interface were determined for the subject liners and compared to the predicate devices.	Diametrical clearances of subject liners must be equal to or greater than that of the predicate liners devices.	Diametrical clearances of the predicate 36mm Pinnacle MOM liner, the comparable ASR MOM bearing groups and the 40 and 44 mm Pinnacle MOM subject liners are presented in Table 1 of Section 2 of this submission. The Diametrical clearances of the subject liners are equal to those of the predicate devices. The test requirements were met.
	3. Cup loosening due to increased friction moment from large MOM interface	Flexion/Extension Frictional Torque Test -- This analysis was conducted in support of the predicate ASR MOM system to measure polar torque of the MOM component. The test was conducted using several MOM bearing pairs ranging from 36-55mm (subject MOM liners fall within this range). The bearing pairs were tested in a MTS Bionix servohydraulic test machine under conditions designed to simulate walking from standstill. Torsion torque was determined for each pair and compared to that measured for simulated gait (flexion/extension).	Torsional torque values for the ASR MOM bearings must be less than or equal to that measured for simulated gait (flexion/extension).	Results of the analysis showed that the larger 55mm MOM bearings exhibited higher torque than the smaller comparison group (28mm Metal-On-Poly). Torsion torques for the 55mm MOM bearing ranged from $0.6\text{--}2.6 \text{ N}\cdot\text{m}$, the 28mm bearing range was $0.1\text{--}0.8 \text{ N}\cdot\text{m}$. Although the torsion torque values were higher for the larger MOM bearings, the bearing moment magnitudes measured for torsional rotation for this group were 2 X's lower than those measured for simulated gait. Therefore it was concluded that the torsion loading failure with the 55mm bearing was less probable than in simulated gait. Since the subject liners are a smaller diameter than the 55mm MOM bearing tested, it is expected that the torsional rotation of these MOM liners will be less than that seen in this study, therefore additional testing was not conducted for the subject liners. The complete "Interfacial Rotational Frictional Torque Test" conducted for the predicate ASR MOM Acetabular System can be found in K040627 (addendum dated May 23, 2005).

0000020

	4. Range of Motion (ROM)	Range of Motion Analysis – ROM for the smallest 40 and 44 mm subject liners was determined Anterior/Posterior (A/P) and Medial/Lateral (M/L). Values were compared to ROM values for the 36mm predicate liners.	ROM of subject liners must be greater than or equal to the predicate liners.	ROM values for the subject liners were greater than those of the predicate liner, the requirements of the test were met. Results are summarized in the table below.																				
				<table><tr><th>LINER(mm)</th><th>A/P ROM</th><th>M/L ROM</th></tr><tr><td>36 x 52</td><td>151°</td><td>142.5°</td></tr><tr><td>40 x 56</td><td>155.7°</td><td>148.1°</td></tr><tr><td>44 x 62</td><td>159.9°</td><td>149.4°</td></tr></table>	LINER(mm)	A/P ROM	M/L ROM	36 x 52	151°	142.5°	40 x 56	155.7°	148.1°	44 x 62	159.9°	149.4°								
LINER(mm)	A/P ROM	M/L ROM																						
36 x 52	151°	142.5°																						
40 x 56	155.7°	148.1°																						
44 x 62	159.9°	149.4°																						
Decreased Outer Diameter of 36mm liner to 50mm	Liner Deformation	Deformation test – Analysis to determine the amount of deformation to the liner under load. The deformation of 3 of the 36mm x 50mm subject liners and 3 of the predicate 36mm x 52mm liners was determined under a 1.81kN load.	The subject liner must experience vertical deflection less than or equal to the vertical deflection shown by the predicate liner. Vertical deflection was considered to be the most critical as the load was applied vertically, deforming the insert into the clearance space between the head and the insert. Horizontal deflection was considered non-critical as it would deform outward and not encroach on the clearance space	The 36mm x 50mm subject liner had an average vertical deflection less than that of the predicate device, the liners met the requirements of the test. The results are summarized in the table below.																				
				<table><tr><th colspan="4">PINNACLE METAL INSERTS</th></tr><tr><th colspan="2">36mm ID x 50mm OD (subject liner)</th><th colspan="2">36mm ID x 52mm OD (predicate)</th></tr><tr><th>AVG Neg Vertical (µm)</th><th>AVG Neg Horizontal (µm)</th><th>AVG Neg Vertical (µm)</th><th>AVG Neg Horizontal (µm)</th></tr><tr><td>-36</td><td>-41</td><td>-64</td><td>-37</td></tr><tr><td>St Dev 7</td><td>St Dev 13</td><td>St Dev 14</td><td>St Dev 4</td></tr></table> <p>Complete test report is on file at DePuy.</p>	PINNACLE METAL INSERTS				36mm ID x 50mm OD (subject liner)		36mm ID x 52mm OD (predicate)		AVG Neg Vertical (µm)	AVG Neg Horizontal (µm)	AVG Neg Vertical (µm)	AVG Neg Horizontal (µm)	-36	-41	-64	-37	St Dev 7	St Dev 13	St Dev 14	St Dev 4
PINNACLE METAL INSERTS																								
36mm ID x 50mm OD (subject liner)		36mm ID x 52mm OD (predicate)																						
AVG Neg Vertical (µm)	AVG Neg Horizontal (µm)	AVG Neg Vertical (µm)	AVG Neg Horizontal (µm)																					
-36	-41	-64	-37																					
St Dev 7	St Dev 13	St Dev 14	St Dev 4																					

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Special 510(k)**Section V****BASIS FOR SUBSTANTIAL EQUIVALENCE:**

The modified Pinnacle Metal-On-Metal Acetabular Cup Liners have the same intended use, indications, manufacturing method, sterilization and packaging as the Pinnacle 36mm and 28mm Acetabular Liners cleared in K003523 and K002883 and the same intended use and indications as the ASR Modular Acetabular Cup System cleared in K040627. The design of the modified Pinnacle Metal-On-Metal Acetabular Cup Liners is similar to the design of the previously cleared Pinnacle Metal-On-Metal liners. The modified liners are offered in a range of sizes (inner and outer diameters) that falls within the range of sizes previously cleared for the ASR Modular Acetabular Cup System. Based on similarities in design, intended use, indications, manufacturing methods, sterilization and packaging DePuy believes that the Pinnacle Metal-On-Metal Acetabular Cup Liners are substantially equivalent to the previously cleared Pinnacle 36 and 28mm metal Acetabular Liners.

Clearance letters for the predicate devices are provided in Exhibit VI.

0000022

EXHIBIT I**Part Numbers****DePuy Pinnacle Metal-On-Metal Acetabular Cup liners**

Description	Part Number
Pinnacle metal ins neut 36ID x 50OD	1218-87-350
Pinnacle metal ins neut 40ID x 56OD	1218-87-456
Pinnacle metal ins neut 40ID x 58OD	1218-87-458
Pinnacle metal ins neut 40ID x 60OD	1218-87-460
Pinnacle metal ins neut 44ID x 62OD	1218-87-462
Pinnacle metal ins neut 44ID x 64OD	1218-87-464
Pinnacle metal ins neut 44ID x 66OD	1218-87-466

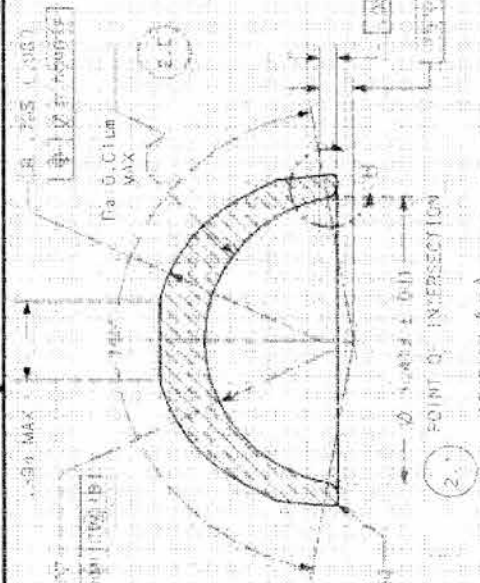
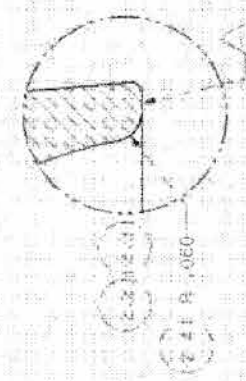
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EXHIBIT II
Engineering Drawings

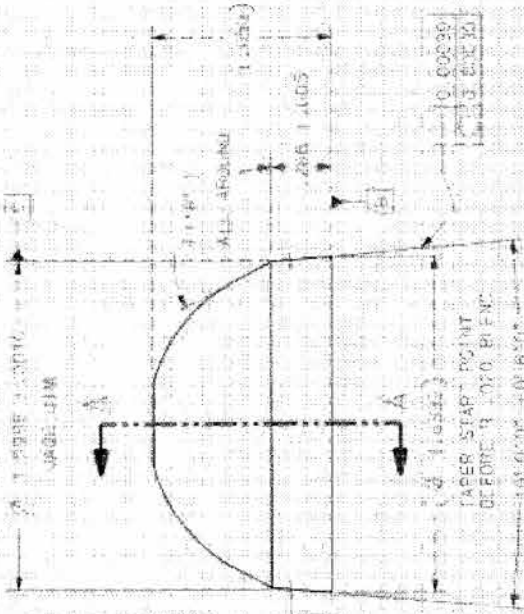
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これは大正十一年の事である。

W. B. BERNARD, JR.

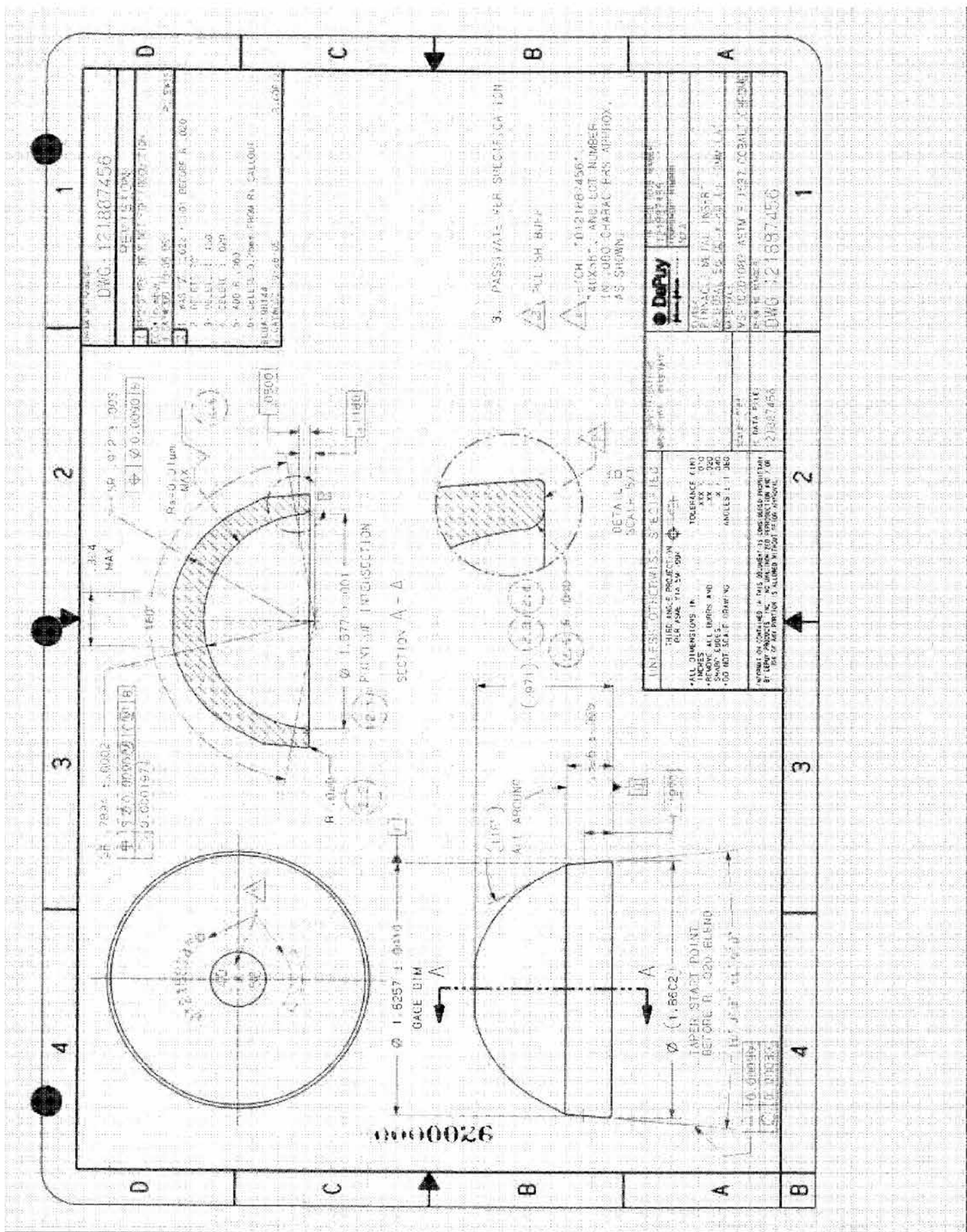
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DePuy
 Orthopaedics
 15000 W. 10th
 Overland Park, KS 66211
 (913) 666-1000

UNLESS OTHERWISE SPECIFIED ALL DIMENSIONS IN INCHES TOLERANCE (IN) XX ± 0.0 XX ± 0.00 XX ± 0.005 XX ± 0.01 XX ± 0.015 XX ± 0.02 XX ± 0.03 XX ± 0.04 XX ± 0.05 XX ± 0.06 XX ± 0.07 XX ± 0.08 XX ± 0.09 XX ± 0.10 XX ± 0.12 XX ± 0.15 XX ± 0.20 XX ± 0.25 XX ± 0.30 XX ± 0.375 XX ± 0.50 XX ± 0.625 XX ± 0.75 XX ± 0.875 XX ± 1.0 XX ± 1.25 XX ± 1.5 XX ± 1.75 XX ± 2.0 XX ± 2.5 XX ± 3.0 XX ± 3.75 XX ± 4.0 XX ± 4.5 XX ± 5.0 XX ± 5.5 XX ± 6.0 XX ± 6.5 XX ± 7.0 XX ± 7.5 XX ± 8.0 XX ± 8.5 XX ± 9.0 XX ± 9.5 XX ± 10.0 XX ± 10.5 XX ± 11.0 XX ± 11.5 XX ± 12.0 XX ± 12.5 XX ± 13.0 XX ± 13.5 XX ± 14.0 XX ± 14.5 XX ± 15.0 XX ± 15.5 XX ± 16.0 XX ± 16.5 XX ± 17.0 XX ± 17.5 XX ± 18.0 XX ± 18.5 XX ± 19.0 XX ± 19.5 XX ± 20.0 XX ± 20.5 XX ± 21.0 XX ± 21.5 XX ± 22.0 XX ± 22.5 XX ± 23.0 XX ± 23.5 XX ± 24.0 XX ± 24.5 XX ± 25.0 XX ± 25.5 XX ± 26.0 XX ± 26.5 XX ± 27.0 XX ± 27.5 XX ± 28.0 XX ± 28.5 XX ± 29.0 XX ± 29.5 XX ± 30.0 XX ± 30.5 XX ± 31.0 XX ± 31.5 XX ± 32.0 XX ± 32.5 XX ± 33.0 XX ± 33.5 XX ± 34.0 XX ± 34.5 XX ± 35.0 XX ± 35.5 XX ± 36.0 XX ± 36.5 XX ± 37.0 XX ± 37.5 XX ± 38.0 XX ± 38.5 XX ± 39.0 XX ± 39.5 XX ± 40.0 XX ± 40.5 XX ± 41.0 XX ± 41.5 XX ± 42.0 XX ± 42.5 XX ± 43.0 XX ± 43.5 XX ± 44.0 XX ± 44.5 XX ± 45.0 XX ± 45.5 XX ± 46.0 XX ± 46.5 XX ± 47.0 XX ± 47.5 XX ± 48.0 XX ± 48.5 XX ± 49.0 XX ± 49.5 XX ± 50.0 XX ± 50.5 XX ± 51.0 XX ± 51.5 XX ± 52.0 XX ± 52.5 XX ± 53.0 XX ± 53.5 XX ± 54.0 XX ± 54.5 XX ± 55.0 XX ± 55.5 XX ± 56.0 XX ± 56.5 XX ± 57.0 XX ± 57.5 XX ± 58.0 XX ± 58.5 XX ± 59.0 XX ± 59.5 XX ± 60.0 XX ± 60.5 XX ± 61.0 XX ± 61.5 XX ± 62.0 XX ± 62.5 XX ± 63.0 XX ± 63.5 XX ± 64.0 XX ± 64.5 XX ± 65.0 XX ± 65.5 XX ± 66.0 XX ± 66.5 XX ± 67.0 XX ± 67.5 XX ± 68.0 XX ± 68.5 XX ± 69.0 XX ± 69.5 XX ± 70.0 XX ± 70.5 XX ± 71.0 XX ± 71.5 XX ± 72.0 XX ± 72.5 XX ± 73.0 XX ± 73.5 XX ± 74.0 XX ± 74.5 XX ± 75.0 XX ± 75.5 XX ± 76.0 XX ± 76.5 XX ± 77.0 XX ± 77.5 XX ± 78.0 XX ± 78.5 XX ± 79.0 XX ± 79.5 XX ± 80.0 XX ± 80.5 XX ± 81.0 XX ± 81.5 XX ± 82.0 XX ± 82.5 XX ± 83.0 XX ± 83.5 XX ± 84.0 XX ± 84.5 XX ± 85.0 XX ± 85.5 XX ± 86.0 XX ± 86.5 XX ± 87.0 XX ± 87.5 XX ± 88.0 XX ± 88.5 XX ± 89.0 XX ± 89.5 XX ± 90.0 XX ± 90.5 XX ± 91.0 XX ± 91.5 XX ± 92.0 XX ± 92.5 XX ± 93.0 XX ± 93.5 XX ± 94.0 XX ± 94.5 XX ± 95.0 XX ± 95.5 XX ± 96.0 XX ± 96.5 XX ± 97.0 XX ± 97.5 XX ± 98.0 XX ± 98.5 XX ± 99.0 XX ± 99.5 XX ± 100.0 XX ± 100.5 XX ± 101.0 XX ± 101.5 XX ± 102.0 XX ± 102.5 XX ± 103.0 XX ± 103.5 XX ± 104.0 XX ± 104.5 XX ± 105.0 XX ± 105.5 XX ± 106.0 XX ± 106.5 XX ± 107.0 XX ± 107.5 XX ± 108.0 XX ± 108.5 XX ± 109.0 XX ± 109.5 XX ± 110.0 XX ± 110.5 XX ± 111.0 XX ± 111.5 XX ± 112.0 XX ± 112.5 XX ± 113.0 XX ± 113.5 XX ± 114.0 XX ± 114.5 XX ± 115.0 XX ± 115.5 XX ± 116.0 XX ± 116.5 XX ± 117.0 XX ± 117.5 XX ± 118.0 XX ± 118.5 XX ± 119.0 XX ± 119.5 XX ± 120.0 XX ± 120.5 XX ± 121.0 XX ± 121.5 XX ± 122.0 XX ± 122.5 XX ± 123.0 XX ± 123.5 XX ± 124.0 XX ± 124.5 XX ± 125.0 XX ± 125.5 XX ± 126.0 XX ± 126.5 XX ± 127.0 XX ± 127.5 XX ± 128.0 XX ± 128.5 XX ± 129.0 XX ± 129.5 XX ± 130.0 XX ± 130.5 XX ± 131.0 XX ± 131.5 XX ± 132.0 XX ± 132.5 XX ± 133.0 XX ± 133.5 XX ± 134.0 XX ± 134.5 XX ± 135.0 XX ± 135.5 XX ± 136.0 XX ± 136.5 XX ± 137.0 XX ± 137.5 XX ± 138.0 XX ± 138.5 XX ± 139.0 XX ± 139.5 XX ± 140.0 XX ± 140.5 XX ± 141.0 XX ± 141.5 XX ± 142.0 XX ± 142.5 XX ± 143.0 XX ± 143.5 XX ± 144.0 XX ± 144.5 XX ± 145.0 XX ± 145.5 XX ± 146.0 XX ± 146.5 XX ± 147.0 XX ± 147.5 XX ± 148.0 XX ± 148.5 XX ± 149.0 XX ± 149.5 XX ± 150.0 XX ± 150.5 XX ± 151.0 XX ± 151.5 XX ± 152.0 XX ± 152.5 XX ± 153.0 XX ± 153.5 XX ± 154.0 XX ± 154.5 XX ± 155.0 XX ± 155.5 XX ± 156.0 XX ± 156.5 XX ± 157.0 XX ± 157.5 XX ± 158.0 XX ± 158.5 XX ± 159.0 XX ± 159.5 XX ± 160.0 XX ± 160.5 XX ± 161.0 XX ± 161.5 XX ± 162.0 XX ± 162.5 XX ± 163.0 XX ± 163.5 XX ± 164.0 XX ± 164.5 XX ± 165.0 XX ± 165.

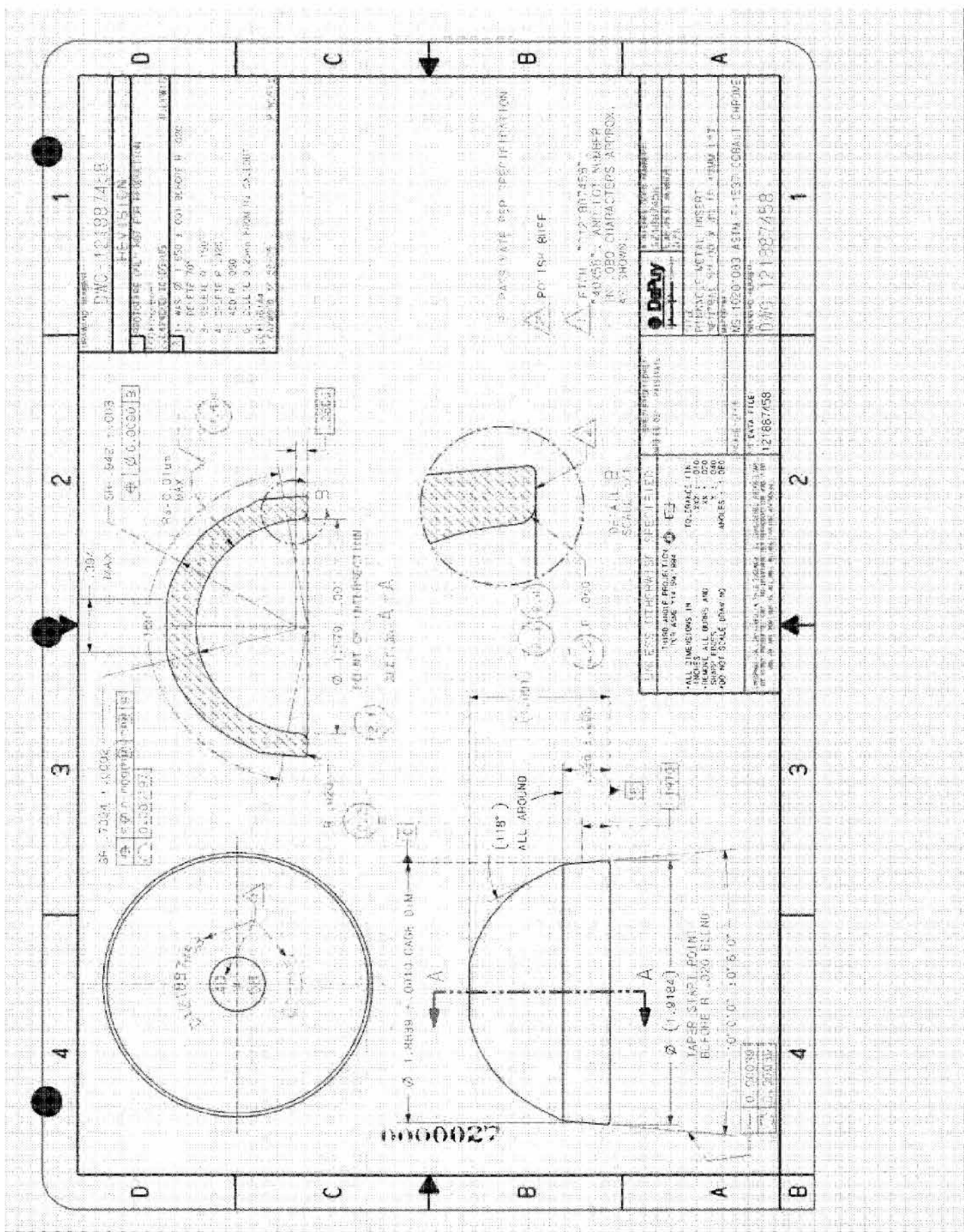
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1. The first step in the process is to identify the problem or issue that needs to be addressed. This involves gathering information and understanding the context of the problem.



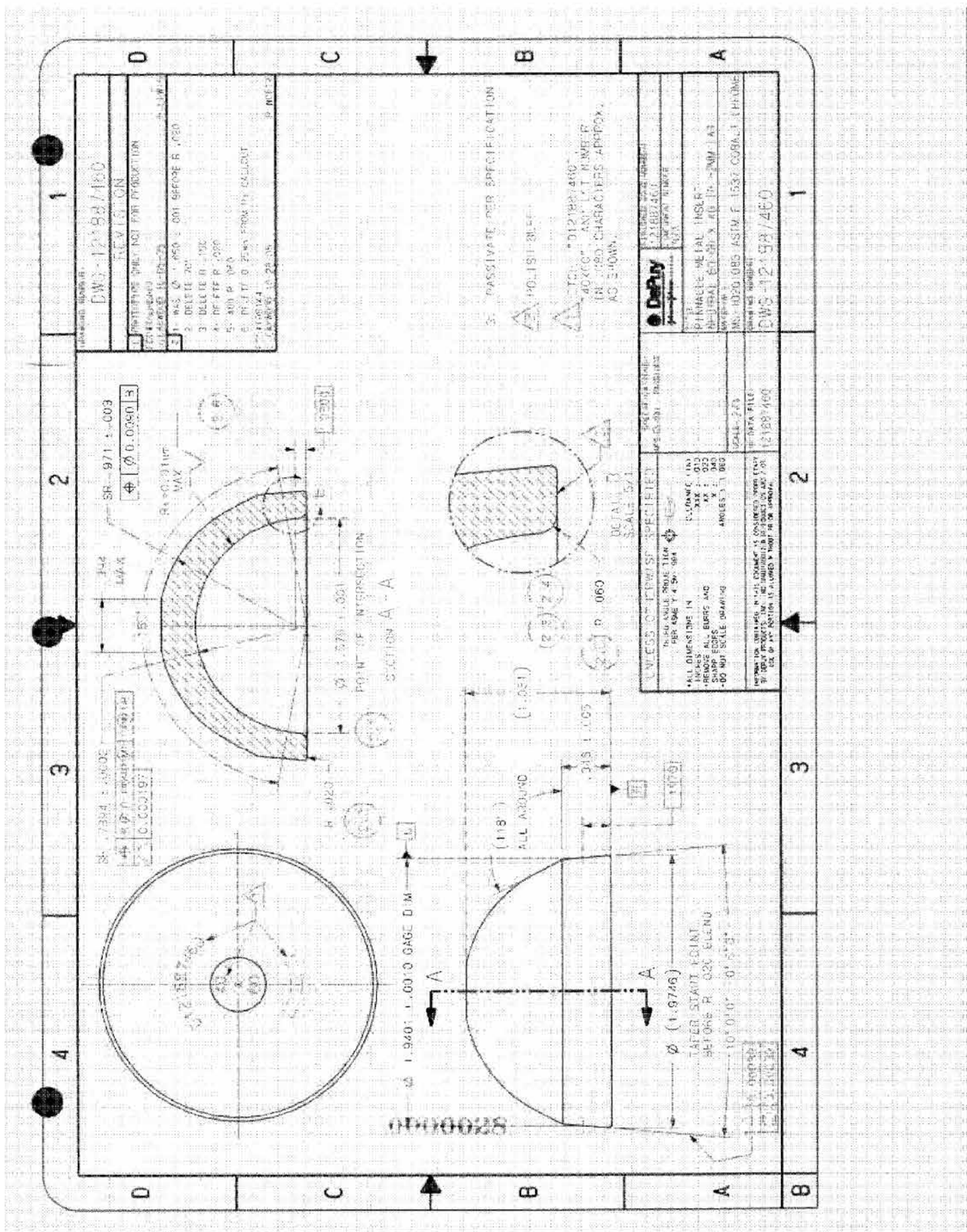
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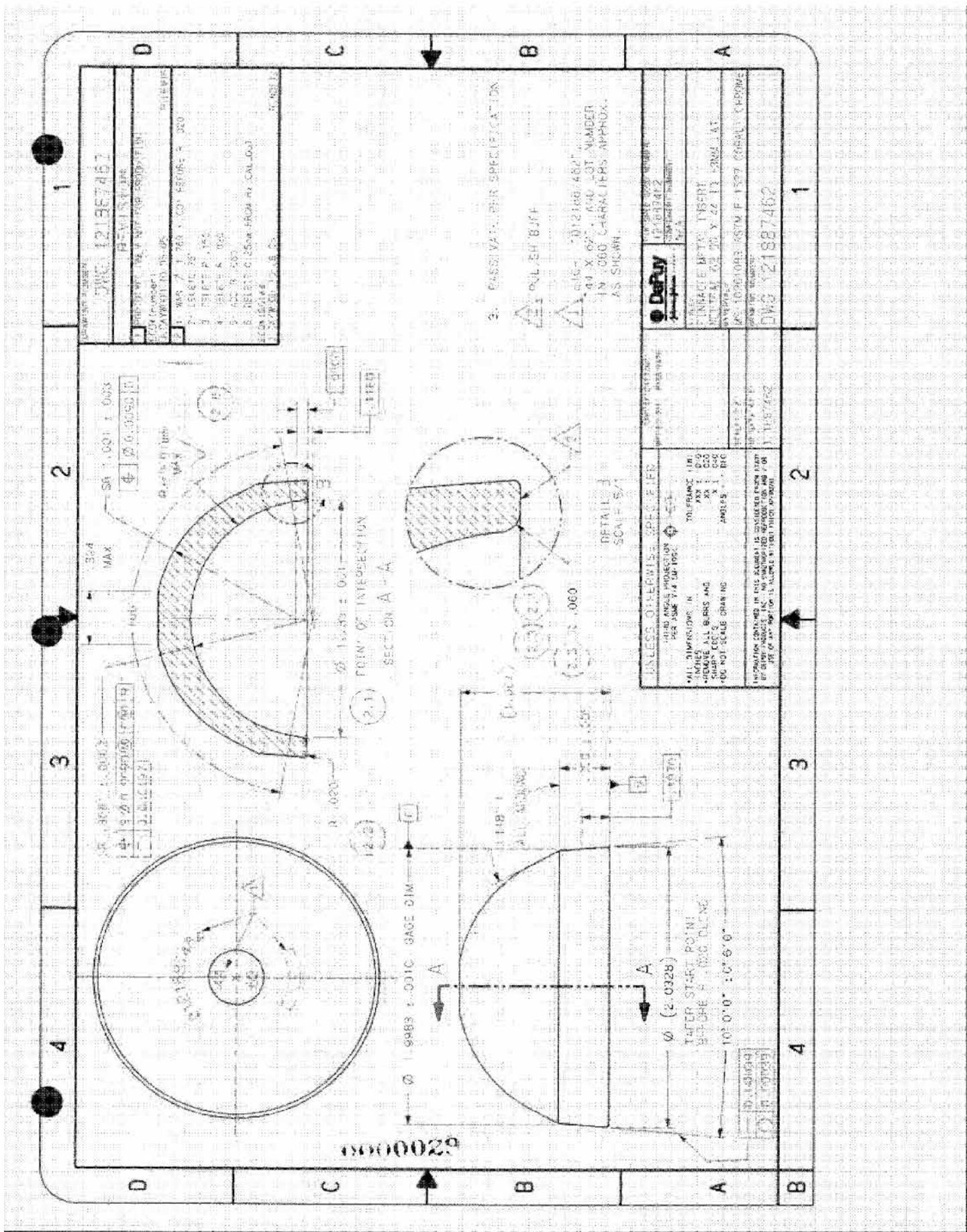
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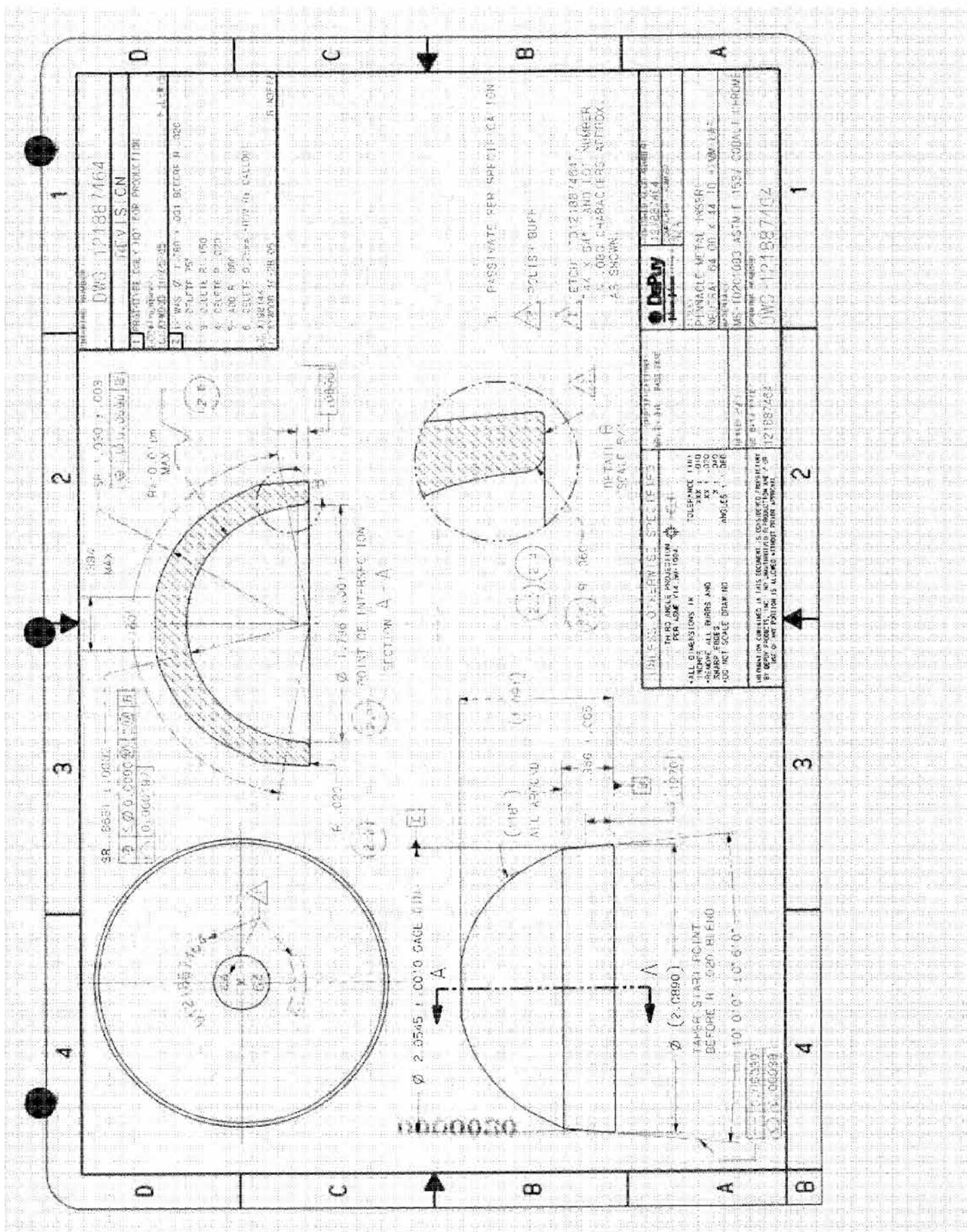


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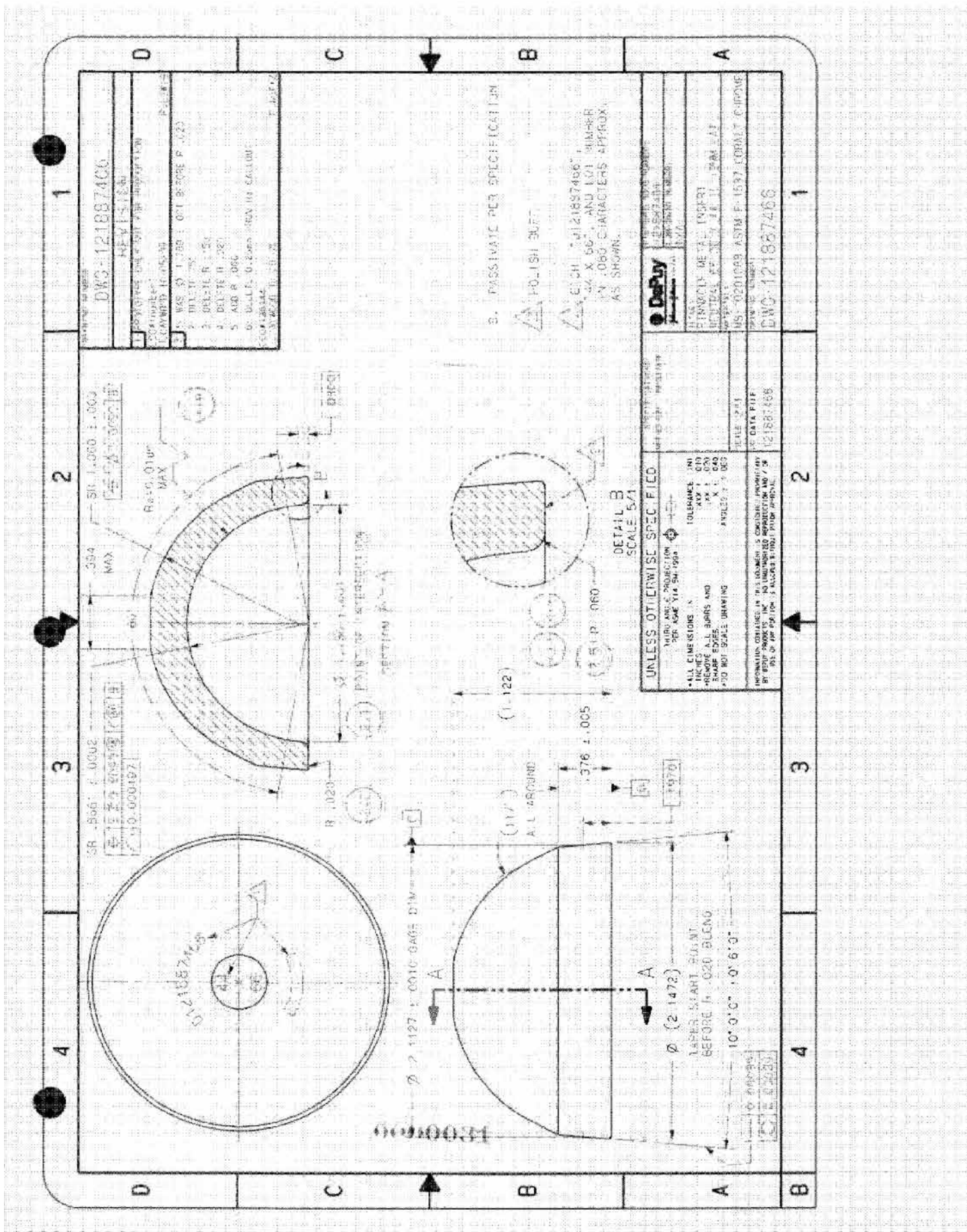


EXHIBIT III**PINNACLE METAL LINER COMPATIBLE COMPONENTS****DePuy Femoral Heads**

Description	Cleared In:
12/14 taper 40-44mm M Spec Co-Cr-Mo Femoral Heads	K060031
11/13 taper 40-44mm M Spec Head Co-Cr-Mo Femoral Heads	K060031
S-ROM 36mm Femoral Heads	K851422, K003523
Articul/eze Ball 36mm Heads	K980513, K003523

DePuy Acetabular Shells

Description	Cleared In:
Pinnacle 100 Series Shells	K001534, K003523
Pinnacle 300 Series Shells	K001534, K003523
Pinnacle Multi-hole Shells	K000306* K001534*
Pinnacle Sector Shells	K001534, K003523
Pinnacle HA Sector	K031495
Pinnacle HA 100	K031495
Standard Profile Shells	K033338
Deep Profile Shells	K033338

*Cleared through internal documentation to this 510(k) in accordance with Blue book Memo #K97-1, documentation on file at DePuy.

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EXHIBIT IV

Draft Labels and Instructions for Use

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


DRAFT LABELS

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ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

		LABEL SPECIFICATION		PAGE: 1 OF 2	
SAMPLE LABEL					
Printer	Astromed	Description	PINNACLE™ metal insert		Code 121887350
LABEL - MAIN PRODUCT					
<p>REF 1218-87-350 LOT 123456789 2 2006-08 STERILE R</p> <p>PINNACLE™ metal insert</p> <div style="display: flex; align-items: center;"> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">Neutral</div> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">36mmID x 60mmOD</div> <div style="border: 1px solid black; padding: 2px; margin-right: 10px;">[Barcode]</div> <div style="text-align: center;">    </div> </div> <p>MATL COBALT CHROME</p> <p>Use only with DePuy femoral heads designated for use with metal inserts. Insert en métal. Neutre 36mmID x 60mmOD. A n'utiliser qu'avec les têtes fémorales DePuy, conçues pour être employées avec des inserts en métal.</p> <p>Metallinserte. Neutraal 36mmID x 60mmOD. Nur mit DePuy Femurköpfen, die autorisieret für den Einsatz mit Metallinserten vorgesehen sind, verwenden.</p> <p>metalen inserten. Neutraal 36mmID x 60mmOD. Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inserten.</p> <p>Inserto metálico. Neutro 36mmID x 60mmOD. De utilizar exclusivamente con le beta femorali DePuy indicate per l'uso con inserti metallici.</p> <p>Inserto metálico. Neutro 36mmID x 60mmOD. Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos.</p> <p>Inserto de metal. Neutro 36mmID x 60mmOD. Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserto de metal.</p> <p>金属製インサート ニュートラル 36mmID x 60mmOD 金属製インサートとの使用を目的としたデューピュースタビライザーヘッドとのみで使用する。 Používajte pouze s femorálními hlavkami typu DePuy vyvinutými pro použití s kovovými vložkami. Căști DePuy stabilizator femurali recomandăm! Do užívania týchto zložiek (vložiek) DePuy priradených k použitiu s metalovými vložkami. Používajte len s femorálnymi hlavkami DePuy určenými na použitie s kovovými vložkami.</p> <p> DePuy Orthopaedics, 700 Orthopaedic Drive, Warsaw, IN 46083-0000, USA   </p> <p>MADE IN UK</p>					
Revision					
Reference					










SOP No. 8-06

0000035

ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

LABEL SPECIFICATION		PAGE: 2 OF 2													
SAMPLE LABEL															
Printer	Zebra	Description	PINNACLE™ metal insert												
		Code	121887350												
<p align="center">LABEL - INNER</p> <p>REF 1218-87-350 LOT 123456789 2006-06 STERILE R</p> <p>PINNACLE™ metal insert</p> <div style="border: 1px solid black; padding: 5px; display: inline-block;"> <p>Neutral 36mmID x 50mmOD</p> </div>  <p>insertion métal Neutre 36mmID x 50mmOD</p> <p>Metalleinlage Neutral 36mmID x 50mmOD</p> <p>metalen insertie Neutral 36mmID x 50mmOD</p> <p>inserto metálico Neutro 36mmID x 50mmOD</p> <p>inserto metálico Neutro 36mmID x 50mmOD</p> <p>insert de metal Neutro 36mmID x 50mmOD</p> <p>金属製インサート ニュートラル 36mmID x 50mmOD</p> <p>MATL CORAL CHROME      </p> <p>DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warren, MI 48090 USA</p> <p align="center">LABEL - DISTRIBUTION & PATIENT</p> <p>REF 1218-87-350 LOT 123456789 2006-06</p> <p>PINNACLE™ Neutral metal insert 36mmID x 50mmOD</p>   <p>DePuy DePuy Orthopaedics, 700 Orthopaedic Drive, Warren, MI 48090 USA STERILE R</p> <table border="1"> <tr> <td>Revision</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Reference</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>				Revision						Reference					
Revision															
Reference															

SOP No. 8-06

0000036

ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

LABEL SPECIFICATION		PAGE: 1 OF 2				
SAMPLE LABEL						
Printer	Astromed	Description	PINNACLE™ metal insert			
		Code	121887456			
LABEL - MAIN PRODUCT						
<p>REF 1218-87-458 LOT 123456789 2006-05 STERILE</p> <p>PINNACLE™ metal insert</p> <table border="1"> <tr> <td>Neutral</td> <td>40mmID x 56mmOD</td> <td></td> </tr> </table> <p>MATL COBALT CHROME</p> <p>Use only with DePuy femoral heads designated for use with metal inserts</p> <p>Insertion métal: Neutre 40mmID x 56mmOD À insérer dans les têtes femorales DePuy conçues pour être employées avec des inserts en métal.</p> <p>Metal einlage: Neutral 40mmID x 56mmOD Nur mit DePuy-Kniegelenken, die ausdrücklich für den Einsatz von Metalleneinsätzen vorgesehen sind, verwenden.</p> <p>Inserten inserte: Neutral 40mmID x 56mmOD Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen indelstukken.</p> <p>Inserto metalico: Neutro 40mmID x 56mmOD Da utilizzare esclusivamente con la testa femorale DePuy indicata per l'uso con inserti metallici.</p> <p>Inserto metálico: Neutro 40mmID x 56mmOD Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos.</p> <p>Inserto de metal: Neutro 40mmID x 56mmOD Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserto de metal.</p> <p>金属製インサート: ニュートラル 40mmID x 56mmOD 金属製インサートとの使用を可能としたデピュー社製大腿骨ヘッドのみご使用下さい。</p> <p>Prostavek pouze s femorálními hlavami typu DePuy vyvinutými pro použití s kovovými vložkami. Čekat DePuy femorální hlavu funkční nestrážbo. Do uchofu tylko z głowicami koleni DePuy przeznaczonymi do użycia z metalowymi wkładkami. Používejte jen s femorálními hlavami DePuy určenými na použití s kovovými vložkami.</p> <p>DePuy, DePuy Orthopaedics, 740 Ochsleppack Drive, Warsaw, IN 46581-0089, USA</p> <p>MADE IN UK</p> <p>PE Only </p>				Neutral	40mmID x 56mmOD	
Neutral	40mmID x 56mmOD					
Rev/Std						
Reference						


SOP No. 8-06

0000037

ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

		LABEL SPECIFICATION SAMPLE LABEL		PAGE: 2 OF 2	
Printer:	Zebra	Description:	PINNACLE™ metal insert	Code:	121887456

LABEL - INNER

REF 1218-87-456 LOT 123456789 2006-06 STERILE R

PINNACLE™
metal insert

Neutral

40mmID x
56mmOD

Insert en métal Neutre 40mmID x 56mmOD

Mettaleinlage Neutral 40mmID x 56mmOD

metalen insertie Neutral 40mmID x 56mmOD

inserto metalico Neutral 40mmID x 56mmOD

inserto metálico Neutral 40mmID x 56mmOD

insert de metal Neutral 40mmID x 56mmOD

金属インサート ニュートラル 40mmID x 56mmOD

MATERIAL
COBALT
CHROME

ISO 13485

2

CE

0066

Lifely Orthopaedics, 100 Orthopaedic Drive,
Austin, TX 78758-1000, USA

LABEL - DISTRIBUTION & PATIENT

REF 1218-87-456 LOT 123456789 2006-06

PINNACLE™

Neutral

metal insert

40mmID x 56mmOD



ATC880218874561P4



REF121887456789

Lifely Orthopaedics, 100 Orthopaedic Drive,
Austin, TX 78758-1000, USA

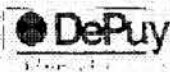
STERILE R

Rev'd Date:					
Reference:					

SOP No. 8-06

0000038

APPENDIX C



LABEL SUBSTITUTION

Prime:

LABEL - MAIN PRODUCT

REF 1218-87-458 LOT 123456789 - 2306-06 STERILE

PINNACLE™
metal insert

Neutral		
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MATL COBALT CHROME

also play with DePuy femoral necks designed for use with total hips.

SECRET

Mit der Begrüßung des Herrn Abgeordneten
Herrn Dr. v. Kottwitz beginnt die Sitzung.
Die Verhandlung wird fortgesetzt.

FILED: 1987-10-20 10:20:00

— 25 —

[Faint, illegible text]

SECRET

1997-1998

[illegible]

1998, 1999, 2000, 2001, 2002, 2003, 2004, 2005, 2006, 2007, 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020, 2021, 2022, 2023, 2024, 2025, 2026, 2027, 2028, 2029, 2030, 2031, 2032, 2033, 2034, 2035, 2036, 2037, 2038, 2039, 2040, 2041, 2042, 2043, 2044, 2045, 2046, 2047, 2048, 2049, 2050, 2051, 2052, 2053, 2054, 2055, 2056, 2057, 2058, 2059, 2060, 2061, 2062, 2063, 2064, 2065, 2066, 2067, 2068, 2069, 2070, 2071, 2072, 2073, 2074, 2075, 2076, 2077, 2078, 2079, 2080, 2081, 2082, 2083, 2084, 2085, 2086, 2087, 2088, 2089, 2090, 2091, 2092, 2093, 2094, 2095, 2096, 2097, 2098, 2099, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 2108, 2109, 2110, 2111, 2112, 2113, 2114, 2115, 2116, 2117, 2118, 2119, 2120, 2121, 2122, 2123, 2124, 2125, 2126, 2127, 2128, 2129, 2130, 2131, 2132, 2133, 2134, 2135, 2136, 2137, 2138, 2139, 2140, 2141, 2142, 2143, 2144, 2145, 2146, 2147, 2148, 2149, 2150, 2151, 2152, 2153, 2154, 2155, 2156, 2157, 2158, 2159, 2160, 2161, 2162, 2163, 2164, 2165, 2166, 2167, 2168, 2169, 2170, 2171, 2172, 2173, 2174, 2175, 2176, 2177, 2178, 2179, 2180, 2181, 2182, 2183, 2184, 2185, 2186, 2187, 2188, 2189, 2190, 2191, 2192, 2193, 2194, 2195, 2196, 2197, 2198, 2199, 2200, 2201, 2202, 2203, 2204, 2205, 2206, 2207, 2208, 2209, 2210, 2211, 2212, 2213, 2214, 2215, 2216, 2217, 2218, 2219, 2220, 2221, 2222, 2223, 2224, 2225, 2226, 2227, 2228, 2229, 2230, 2231, 2232, 2233, 2234, 2235, 2236, 2237, 2238, 2239, 2240, 2241, 2242, 2243, 2244, 2245, 2246, 2247, 2248, 2249, 2250, 2251, 2252, 2253, 2254, 2255, 2256, 2257, 2258, 2259, 2260, 2261, 2262, 2263, 2264, 2265, 2266, 2267, 2268, 2269, 2270, 2271, 2272, 2273, 2274, 2275, 2276, 2277, 2278, 2279, 2280, 2281, 2282, 2283, 2284, 2285, 2286, 2287, 2288, 2289, 2290, 2291, 2292, 2293, 2294, 2295, 2296, 2297, 2298, 2299, 2300, 2301, 2302, 2303, 2304, 2305, 2306, 2307, 2308, 2309, 2310, 2311, 2312, 2313, 2314, 2315, 2316, 2317, 2318, 2319, 2320, 2321, 2322, 2323, 2324, 2325, 2326, 2327, 2328, 2329, 2330, 2331, 2332, 2333, 2334, 2335, 2336, 2337, 2338, 2339, 2340, 2341, 2342, 2343, 2344, 2345, 2346, 2347, 2348, 2349, 2350, 2351, 2352, 2353, 2354, 2355, 2356, 2357, 2358, 2359, 2360, 2361, 2362, 2363, 2364, 2365, 2366, 2367, 2368, 2369, 2370, 2371, 2372, 2373, 2374, 2375, 2376, 2377, 2378, 2379, 2380, 2381, 2382, 2383, 2384, 2385, 2386, 2387, 2388, 2389, 2390, 2391, 2392, 2393, 2394, 2395, 2396, 2397, 2398, 2399, 2400, 2401, 2402, 2403, 2404, 2405, 2406, 2407, 2408, 2409, 2410, 2411, 2412, 2413, 2414, 2415, 2416, 2417, 2418, 2419, 2420, 2421, 2422, 2423, 2424, 2425, 2426, 2427, 2428, 2429, 2430, 2431, 2432, 2433, 2434, 2435, 2436, 2437, 2438, 2439, 2440, 2441, 2442, 2443, 2444, 2445, 2446, 2447, 2448, 2449, 2450, 2451, 2452, 2453, 2454, 2455, 2456, 2457, 2458, 2459, 2460, 2461, 2462, 2463, 2464, 2465, 2466, 2467, 2468, 2469, 2470, 2471, 2472, 2473, 2474, 2475, 2476, 2477, 2478, 2479, 2480, 2481, 2482, 2483, 2484, 2485, 2486, 2487, 2488, 2489, 2490, 2491, 2492, 2493, 2494, 2495, 2496, 2497, 2498, 2499, 2500, 2501, 2502, 2503, 2504, 2505, 2506, 2507, 2508, 2509, 2510, 2511, 2512, 2513, 2514, 2515, 2516, 2517, 2518, 2519, 2520, 2521, 2522, 2523, 2524, 2525, 2526, 2527, 2528, 2529, 2530, 2531, 2532, 2533, 2534, 2535, 2536, 2537, 2538, 2539, 2540, 2541, 2542, 2543, 2544, 2545, 2546, 2547, 2548, 2549, 2550, 2551, 2552, 2553, 2554, 2555, 2556, 2557, 2558, 2559, 2560, 2561, 2562, 2563, 2564, 2565, 2566, 2567, 2568, 2569, 2570, 2571, 2572, 2573, 2574, 2575, 2576, 2577, 2578, 2579, 2580, 2581, 2582, 2583, 2584, 2585, 2586, 2587, 2588, 2589, 2590, 2591, 2592, 2593, 2594, 2595, 2596, 2597, 2598, 2599, 2600, 2601, 2602, 2603, 2604, 2605, 2606, 2607, 2608, 2609, 2610, 2611, 2612, 2613, 2614, 2615, 2616, 2617, 2618, 2619, 2620, 2621, 2622, 2623, 2624, 2625, 2626, 2627, 2628, 2629, 2630, 2631, 2632, 2633, 2634, 2635, 2636, 2637, 2638, 2639, 2640, 2641, 2642, 2643, 2644, 2645, 2646, 2647, 2648, 2649, 2650, 2651, 2652, 2653, 2654, 2655, 2656, 2657, 2658, 2659, 2660, 2661, 2662, 2663, 2664, 2665, 2666, 2667, 2668, 2669, 2670, 2671, 2672, 2673, 2674, 2675, 2676, 2677, 2678, 2679, 26

Figure 1

FOIA b 7(D), (b) (5) DPP, (b) (5) ACP - - 2, 6 -

Case No. 1, 1911-1912, 1913-1914, 1915-1916, 1917-1918, 1919-1920, 1921-1922, 1923-1924, 1925-1926, 1927-1928, 1929-1930, 1931-1932, 1933-1934, 1935-1936, 1937-1938, 1939-1940, 1941-1942, 1943-1944, 1945-1946, 1947-1948, 1949-1950, 1951-1952, 1953-1954, 1955-1956, 1957-1958, 1959-1960, 1961-1962, 1963-1964, 1965-1966, 1967-1968, 1969-1970, 1971-1972, 1973-1974, 1975-1976, 1977-1978, 1979-1980, 1981-1982, 1983-1984, 1985-1986, 1987-1988, 1989-1990, 1991-1992, 1993-1994, 1995-1996, 1997-1998, 1999-2000, 2001-2002, 2003-2004, 2005-2006, 2007-2008, 2009-2010, 2011-2012, 2013-2014, 2015-2016, 2017-2018, 2019-2020, 2021-2022, 2023-2024, 2025-2026, 2027-2028, 2029-2030, 2031-2032, 2033-2034, 2035-2036, 2037-2038, 2039-2040, 2041-2042, 2043-2044, 2045-2046, 2047-2048, 2049-2050, 2051-2052, 2053-2054, 2055-2056, 2057-2058, 2059-2060, 2061-2062, 2063-2064, 2065-2066, 2067-2068, 2069-2070, 2071-2072, 2073-2074, 2075-2076, 2077-2078, 2079-2080, 2081-2082, 2083-2084, 2085-2086, 2087-2088, 2089-2090, 2091-2092, 2093-2094, 2095-2096, 2097-2098, 2099-2100, 2101-2102, 2103-2104, 2105-2106, 2107-2108, 2109-2110, 2111-2112, 2113-2114, 2115-2116, 2117-2118, 2119-2120, 2121-2122, 2123-2124, 2125-2126, 2127-2128, 2129-2130, 2131-2132, 2133-2134, 2135-2136, 2137-2138, 2139-2140, 2141-2142, 2143-2144, 2145-2146, 2147-2148, 2149-2150, 2151-2152, 2153-2154, 2155-2156, 2157-2158, 2159-2160, 2161-2162, 2163-2164, 2165-2166, 2167-2168, 2169-2170, 2171-2172, 2173-2174, 2175-2176, 2177-2178, 2179-2180, 2181-2182, 2183-2184, 2185-2186, 2187-2188, 2189-2190, 2191-2192, 2193-2194, 2195-2196, 2197-2198, 2199-2200, 2201-2202, 2203-2204, 2205-2206, 2207-2208, 2209-2210, 2211-2212, 2213-2214, 2215-2216, 2217-2218, 2219-2220, 2221-2222, 2223-2224, 2225-2226, 2227-2228, 2229-2230, 2231-2232, 2233-2234, 2235-2236, 2237-2238, 2239-2240, 2241-2242, 2243-2244, 2245-2246, 2247-2248, 2249-2250, 2251-2252, 2253-2254, 2255-2256, 2257-2258, 2259-2260, 2261-2262, 2263-2264, 2265-2266, 2267-2268, 2269-2270, 2271-2272, 2273-2274, 2275-2276, 2277-2278, 2279-2280, 2281-2282, 2283-2284, 2285-2286, 2287-2288, 2289-2290, 2291-2292, 2293-2294, 2295-2296, 2297-2298, 2299-2300, 2301-2302, 2303-2304, 2305-2306, 2307-2308, 2309-2310, 2311-2312, 2313-2314, 2315-2316, 2317-2318, 2319-2320, 2321-2322, 2323-2324, 2325-2326, 2327-2328, 2329-2330, 2331-2332, 2333-2334, 2335-2336, 2337-2338, 2339-2340, 2341-2342, 2343-2344, 2345-2346, 2347-2348, 2349-2350, 2351-2352, 2353-2354, 2355-2356, 2357-2358, 2359-2360, 2361-2362, 2363-2364, 2365-2366, 2367-2368, 2369-2370, 2371-2372, 2373-2374, 2375-2376, 2377-2378, 2379-2380, 2381-2382, 2383-2384, 2385-2386, 2387-2388, 2389-2390, 2391-2392, 2393-2394, 2395-2396, 2397-2398, 2399-2400, 2401-2402, 2403-2404, 2405-2406, 2407-2408, 2409-2410, 2411-2412, 2413-2414, 2415-2416, 2417-2418, 2419-2420, 2421-2422, 2423-2424, 2425-2426, 2427-2428, 2429-2430, 2431-2432, 2433-2434, 2435-2436, 2437-2438, 2439-2440, 2441-2442, 2443-2444, 2445-2446, 2447-2448, 2449-2450, 2451-2452, 2453-2454, 2455-2456, 2457-2458, 2459-2460, 2461-2462, 2463-2464, 2465-2466, 2467-2468, 2469-2470, 2471-2472, 2473-2474, 2475-2476, 2477-2478, 2479-2480, 2481-2482, 2483-2484, 2485-2486, 2487-2488, 2489-2490, 2491-2492, 2493-2494, 2495-2496, 2497-2498, 2499-2500, 2501-2502, 2503-2504, 2505-2506, 2507-2508, 2509-2510, 2511-2512, 2513-2514, 2515-2516, 2517-2518, 2519-2520, 2521-2522, 2523-2524, 2525-2526, 2527-2528, 2529-2530, 2531-2532, 2533-2534, 2535-2536, 2537-2538, 2539-2540, 2541-2542, 2543-2544, 2545-2546, 2547-2548, 2549-2550, 2551-2552, 2553-2554, 2555-2556, 2557-2558, 2559-2560, 2561-2562, 2563-2564, 2565-2566, 2567-2568, 2569-2570, 2571-2572, 2573-2574, 2575-2576, 2577-2578, 2579-2580, 2581-2582, 2583-2584, 2585-2586, 2587-2588, 2589-2590, 2591-2592, 2593-2594, 2595-2596, 2597-2598, 2599-2600, 2601-2602, 2603-2604, 2605-2606, 2607-2608, 2609-2610, 2611-2612, 2613-2614, 2615-2616, 2617-2618, 2619-2620, 2621-2622, 2623-2624, 2625-2626, 2627-2628, 2629-2630, 2631-2632, 2633-2634, 2635-2636, 2637-2638, 2639-2640, 2641-2642, 2643-2644, 2645-2646, 2647-2648, 2649-2650, 2651-2652, 2653-2

DATE OF BIRTH: 01/01/1967

FOIA b (7) - (D) - 1.0 - 262



SECRET

 $\boxed{R_0 \cdot Q = 1\gamma}$

MADE IN UK

583] *No. 8-106*

APPENDIX C



LABEL SPECIFICATION

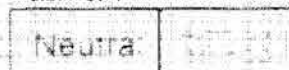
PAGE 2 OF 2

Printer

Code 1218P7458

LABEL - INNER

REF 1218-87-458 LOT 123456789 2006-06

PINNACLE™
metal insert

Insertion depth: Neutra 40mm D x 55mm OD

Metal package: Neutra 40mm D x 55mm OD

Metal package: Neutra 40mm D x 55mm OD

Metal package: Neutra 40mm D x 55mm OD

Metal package: Neutra 40mm D x 55mm OD

Metal package: Neutra 40mm D x 55mm OD

40mm D x 55mm OD

COBALT
CHROMEDePuy, a Division of Johnson & Johnson
New York, NY 10017, USA

LABEL - DISTRIBUTION & PATIENT

REF 1218-87-458 LOT 123456789 2006-06

PINNACLE™

metal insert

DePuy, a Division of Johnson & Johnson
New York, NY 10017, USA

STERILE R

0000040

SOP No. 8-06

APPENDIX C



LABEL SPECIFICATION

PAGE: 1 OF 2

Printer

Astronac

Description

PINNACLE™ metal insert

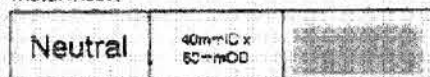
Code

121887460

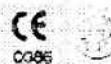
LABEL - MAIN PRODUCT

REF 1218-87-460 LOT 123456789 2006-06

STERILE

PINNACLE™
metal insert

MATERIAL COBALT CHROME



Use only with DePuy femoral heads designated for use with metal inserts

insérer en métal: neutre 40mm ID x 60mm OD

A utiliser uniquement avec les têtes fémorales DePuy conçues pour être employées avec des inserts en métal

Metallem age: Neutro 40mm ID x 60mm OD

Nur mit DePuy Femurköpfen, die ausdrücklich für den Einsatz mit Metallinserten vorgesehen sind, verwenden

metalen inserta: Neutro 40mm ID x 60mm OD

Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inserten

inserto metálico: Neutro 40mm ID x 60mm OD

Devi utilizzarsi esclusivamente con le teste femorali DePuy indicate per uso con impianti metallici

inserto metálico: Neutro 40mm ID x 60mm OD

Usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos

insert de metal: Neutro 40mm ID x 60mm OD

Utilize apenas com cabeças femorais DePuy indicadas para utilização com inserto de metal

金属材料: Neutro 40mm ID x 60mm OD

金属材料: Neutro 40mm ID x 60mm OD

Používat pouze s hlavami femorálními DePuy určenými pro použití s kovovými implantáty

Gesk DePuy trochiseiten femur koppen bestemd voor gebruik met metalen inserten

Os używać tylko z głowami fémoralnymi DePuy przeznaczonymi do użycia z metalowymi wszczepami

Používejte jen s femorálními hlavami DePuy určenými pro použití s kovovými vložkami

DePuy Orthopaedics, 1100 Birchwood Drive
Warsaw, IN 46080-0001 USA

Rx Only

MADE IN UK

Revision
Reference

ECO 208607

0000041

SOP No. 8-06

APPENDIX C



LABEL SPECIFICATION

Printer

Zebra

Description

PINNACLE™ metal insert

Code

121857450

LABEL - INNER

REF 1218-87-460 LOT 123456789 2006-06 **STERILE**PINNACLE™
metal insert

Neutral	40mmID x 60mmOD
---------	--------------------



insert en metal. Neutre 40mmID x 60mmOD

Metalionlage. Neutral 40mmID x 60mmOD

inserto en metal. Neutro 40mmID x 60mmOD

inserto metalico. Neutro 40mmID x 60mmOD

inserto metalico. Neutro 40mmID x 60mmOD

inserto de metal. Neutro 40mmID x 60mmOD

中込器 (メタル) - 中込器 (メタル) 40mmID x 60mmOD

MATERIAL COBALT
CHROME

Rx Only



CE

0086

DePuy Orthopaedics, 700 Orthopaedic Drive
Warsaw, IN 46081-0001 USA

LABEL - DISTRIBUTION & PATIENT

REF 1218-87-460 LOT 123456789 2006-06

PINNACLE™
metal insertNeutral
40mmID x 60mmODDePuy Orthopaedics, 700 Orthopaedic Drive
Warsaw, IN 46081-0001 USA**STERILE**

Revision

Reference

20060307


0000042






SOP No. 8-06

ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

		LABEL SPECIFICATION SAMPLE LABEL		PAGE: 1 OF 2	
Printer:	Astromed	Description:	PINNACLE™ metal insert	Code:	121887462

LABEL - MAIN PRODUCT					
REF 1218-87-482 LOT 123456789 2008-06 STERILE					
PINNACLE™ metal insert					
Neutral		44mmID x 82mmOD			
MATL COBALT-CHROME					
Use only with DePuy femoral heads designated for use with metal inserts insert en métal: Neutre 44mmID x 82mmOD A n'utiliser qu'avec les têtes fémorales DePuy, conçues pour être employées avec des inserts en métal. Metallanlage: Neutral 44mmID x 82mmOD Nur mit DePuy Femurköpfen, die ausdrücklich für den Einsatz mit Metallanlagen vorgesehen sind, verwenden. metalen inserten: Neutraal 44mmID x 82mmOD Uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen rozestukken. Inserto metálico: Neutro 44mmID x 82mmOD De utilizar exclusivamente con la base femoral DePuy indicada por fuso con inserto metálico. Inserto metálico: Neutro 44mmID x 82mmOD Usar sólo con las cabezas femorales DePuy indicadas para uso con insertos metálicos. Insert de metal: Neutro 44mmID x 82mmOD Utiliza apenas com cabeças femorais DePuy indicadas para utilização com inserts de metal. 金属面インサート ニュートラル 44mmID x 82mmOD 金属面インサートとの使用を目的としたデピュー 広頭大骨節ヘッドとのみご使用下さい。 Používajte pouze s femorálními hlavami typu DePuy vyvinutými pro použití s kovovými vložkami. csak DePuy térbelésekkel együtt használható. Do użytku tylko z głowkami kości udowej DePuy przeznaczonymi do użytku z metalowymi włożkami. Používajte len s femorálnymi hlavami DePuy určenými na použitie s kovovými vložkami.					
 DePuy, DePuy 2200000000, 700 Orinopas Drive, Warsaw, IN 46581-0988, USA					
MADE IN UK					

Needing					
Reference					








SOP No. 8-06

0000043

ECO 194727 Appendix A

SOP-8-10 Rev 5

APPENDIX C

DePuy		LABEL SPECIFICATION		PAGE: 2 OF 2													
SAMPLE LABEL																	
Printer	Zebra	Description	PINNACLE™ metal insert	Code	121887462												
LABEL - INNER																	
REF 1218-87-482 LOT 123456789 2006-08 STERILE R																	
PINNACLE™ metal insert																	
Neutral		44mmID x 62mmOD															
Insert en métal Neutre 44mmID x 62mmOD																	
Metalleinslage Neutral 44mmID x 62mmOD																	
metalen insertie Neutral 44mmID x 62mmOD																	
inserto metálico Neutro 44mmID x 62mmOD																	
inserto metálico Neutro 44mmID x 62mmOD																	
insert de metal Neutro 44mmID x 62mmOD																	
金属製インサート ニュートラル 44mmID x 62mmOD																	
																	
   																	
DePuy Orthopaedics, 150 Orthopaedic Drive, Warren, NJ 07059-0001, USA																	
LABEL - DISTRIBUTION & PATIENT																	
REF 1218-87-482 LOT 123456789 2006-08																	
PINNACLE™ Neutral																	
metal insert 44mmID x 62mmOD																	
																	
																	
DePuy Orthopaedics, 150 Orthopaedic Drive, Warren, NJ 07059-0001, USA																	
STERILE R																	
<table border="1"> <tr> <td>Keywords</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>Reference</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>						Keywords						Reference					
Keywords																	
Reference																	

SOP No. 8-06

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APPENDIX C



LABEL SPECIFICATION

PAGE 1 OF 2

Printer	Astronoid	Description	PINNACLE™ metal insert	Code	121887484
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LABEL - MAIN PRODUCT

REF 1218-87-484 LOT 123456789 2008-06

STERILE

PINNACLE™
metal insert

Neutral

44mmD x
64mmOD

0085

MATERIAL COBALT CHROME

Use only with DePuy Femoral heads designated for use with metal inserts

Insert en métal. Neutre 44mmD x 64mmOD

A N'utiliser qu'avec les têtes femorales DePuy conçues pour être employées avec des inserts en métal.

Metallene Insette. Neutral 44mmD x 64mmOD

Nur mit DePuy Femurköpfen die ausdrücklich für den Einsatz mit Metallene Insetten vorgesehen sind verwenden.

Metalen Insette. Neutral 44mmD x 64mmOD

uitsluitend gebruiken met DePuy femurkoppen bestemd voor gebruik met metalen inzetstukken.

Inserto metalico. Neutro 44mmD x 64mmOD

Da utilizzare esclusivamente con le teste femorali DePuy indicate per uso con inserti metallici.

Inserto metalico. Neutro 44mmD x 64mmOD

usar sólo con las cabezas femorales DePuy designadas para su uso con insertos metálicos.

Inserto de metal. Neutro 44mmD x 64mmOD

Utilize apenas com cabeças femorais DePuy, tidas para utilização com insertos de metal.

金属製インサート。ニュートラル 44mmD x 64mmOD

※金属インサートは、必ず「DePuy」の指示に従って使用してください。

Používajte pouze s femorálními hlavami typu DePuy vyvinutými pro použití kovových vložek.

Ne DePuy femorálních hlavek používajte.

DePuy a tylko z głowic i kółek DePuy przeznaczonych do użycia z metalowymi wkładkami.

Používajte len s femorálnymi hlavami DePuy určenými na použitie kovových vložkami.

DePuy Orthopaedics Inc. 700 Quince Orchard Drive
Gaithersburg, MD 20878, USA

MADE IN UK



Revision	1
Reference	DOC/233607

0000045

SOP No. 8-06

APPENDIX C



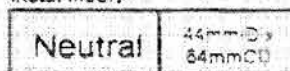
LABEL SPECIFICATION

PAGE 2 OF 2

Printer	Label	Description	PINNACLE™ metal insert	Code	121887482
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LABEL - INNER

REF 1218-87-464 LOT 123456789 2006-06 STERILE R

PINNACLE™
metal insert

insertion meta: Neutre 44mm D x 64mm OD

Métallentage: Neutre 44mm D x 64mm OD

metalen insertie: Neutraal 44mm D x 64mm OD

inserto metalico: Neutro 44mm D x 64mm OD

inserto metalico: Neutro 44mm D x 64mm OD

insert de metal: Neutro 44mm D x 64mm OD

insert de metal: Neutro 44mm D x 64mm OD

MATERIAL COBALT
CHROMER₂ Only

C086

DePuy Orthopaedics, 700 Orthopaedic Drive
Warren, IN 46581-0920, USA

LABEL - DISTRIBUTION & PATIENT

REF 1218-87-464 LOT 123456789 2006-06

PINNACLE™

Neutral

metal insert

44mm D x 64mm OD

DePuy Orthopaedics, 700 Orthopaedic Drive
Warren, IN 46581-0920, USA

STERILE R

Revision
Reference

100 26669

0000046

SOP No. 8-06

APPENDIX C



LABEL SPECIFICATION

Number	Part	Description	Part Number	Lot Number
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LABEL - INNER

REF: 1218-87-456 LOT: 123456789 DATE: 2006-06

PINNACLE™
metal insert

Neutral

Insertion metal: Neutral 44mm D x 65mm OD

Metalleinschub: Neutral 44mm D x 65mm OD

metalleinsetz: Neutral 44mm D x 65mm OD

inserto metal: Neutral 44mm D x 65mm OD

inserto metalico: Neutral 44mm D x 65mm OD

Pinschiebmetail: Neutral 44mm D x 65mm OD

44mm D x 65mm OD

 DEPUY
 CHROME
DePuy Orthopaedics, Inc. 11100 Westpark Drive
Austin, Texas 78750 USA

LABEL - DISTRIBUTION & PATIENT

REF: 1218-87-456 LOT: 123456789 DATE: 2006-06

PINNACLE™
metal insertDePuy Orthopaedics, Inc. 11100 Westpark Drive
Austin, Texas 78750 USA

STERILE

0000048

SOP No. 8-06

DRAFT INSTRUCTIONS FOR USE (IFU)

0000049

DePuy Pinnacle Acetabular Metal Inserts

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Description

The DePuy Pinnacle Acetabular Cup System is comprised of a metal acetabular shell designed to accept alternative bearing inserts. The Pinnacle metal insert mechanically locks with the metal shell via a taper junction.

Do not mix inserts and shells from different systems. Pinnacle Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.

Indications

Pinnacle Acetabular Cups are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

For metal-on-metal articulation, Pinnacle Acetabular Inserts are intended for use only with DePuy 28mm, 36mm, 40mm and 44mm diameter Co-Cr-Mo femoral heads labelled for metal-on-metal use. Inserts with a 28mm inner diameter should be used with 28mm femoral heads only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads only. Inserts with a 40mm inner diameter should be used with the 40mm femoral heads only. Inserts with a 44mm inner diameter should be used with the 44mm femoral heads only.

Information for Use

An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual on use of the instrument system and implantation of the prosthesis. A special instrument is provided to enable the surgeon to remove the insert once it has been fitted in place.

Contraindications

Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear. Postoperative care is extremely important. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissible. Early motion and load bearing should be carefully monitored.

mm0050

This implant should not be used with other manufacturers' components. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure. Use the Pinnacle metal insert only with the Pinnacle Acetabular Shell.

The inner diameter of the insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure.

Metal-on-metal articulation must utilize DePuy heads especially designed for this purpose

Precautions

To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surface before the final decision to implant has been made.

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the shell it may become loose.

Adverse Effects

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements.

Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible.

There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases.

Serious adverse effects may necessitate surgical intervention.

Sterility and Handling

Pinnacle acetabular metal inserts are supplied sterile by exposure to gamma irradiation.

0000051

DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.

Components may not be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous surface.

The care and handling of porous coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis.

The package should be opened only after the correct size has been determined, as opened packages may not be returned for credit.

Further information is available from your DePuy representative on request.

0000052

EXHIBIT V

Hip Simulator Wear Study

0000053

Introduction

The metal-on-metal hip has shown greater wear reduction than the metal-on-polyethylene hip system [1]. Lab simulation showed that most of the metal-on-metal wear occurred during the break-in period [2]. Therefore, it is important to reduce the initial wear of a modern metal-on-metal hip system. Fluid film lubrication formation has been recognized as one of the key factors to wear reduction. Increasing the head size and reducing the diametrical clearance will help establishing fluid film lubrication [3]. Other benefits of large head size include increased range of motion and enhanced stability from hip joint dislocation.

The purpose of this study was to demonstrate the effect of implant diameters on the wear of a modern metal-on-metal hip implant using a hip simulation machine.

Materials and Methods

High-carbon CoCrMo (ASTM F1537) wrought femoral head components and acetabular inserts were tested. The test specimens were arranged in two groups (four sets for each) according to their nominal head/insert sizes, including Group A: 28 mm (the small head), and group B: 44 mm (the large head) (Table 1). The actual diameters for the implants were measured using a CMM (Brown & Sharpe, North Kingstown, RI). Each diameter was calculated by randomly taking 50 points on the spherical surface of the implants. The diametrical clearances were calculated as the difference between the diameters of the inserts and heads. A head-and-insert match was performed to ensure the similar clearance for each group (Table 2). The initial diametrical clearance for the small head group and the large head group were $65.5 \pm 4.4 \mu\text{m}$, and $94.2 \pm 7.3 \mu\text{m}$, respectively. These values were representative of the manufacturing specifications defined for the products. Surface metrology was performed using a NewView 5000 Interferometer (Zygo Corporation, Middlefield, CT) with a scan area of 0.387 mm^2 and a scan length of $20 \mu\text{m}$. Five locations were measured, including the apex and four locations at the 23-degree (each 90-degree apart) from the apex of the specimens. All articulating surfaces were initially polished to an Ra of $0.01 \mu\text{m}$ or less.

The wear test was performed on an 8-station hip joint simulator (MTS, Eden Prairie, MN) using the Paul-type physiological loading (3000 N max, $\pm 23^\circ$ biaxial rocking motion at 1 Hz), with an inverted position (i.e., the head located on top of the insert) for 6 million cycles. The interface was lubricated with bovine serum (HyClone Lab, Logan, UT), which contained 0.2% sodium azide and 20mM EDTA. The protein concentration was 17 mg/ml (approximately 25% of original serum concentration). Wear was assessed by measuring the weight loss every half million cycles. The weight loss was converted to volumetric wear

using a density of 8.86 g/cm³ [2]. One additional weighing was performed at 0.25 million cycles (MC) to observe the early wear-in of the components. The surface morphology was evaluated using light microscopy.

Table 1. Head and Insert Specifications and Part Numbers

Group ID	A (Small Head)	B (Large Head)
Head	Articul/eze (28mm 12/14 +5) (1365-12-500)	Metal Head (44mm 12/14 +5) (1365-69-000 rev 1)
Insert	Metal Insert 28x52 (1218-89-152)	Metal Insert 44x66 (1218-87-466)
Shell	52mm Pinnacle (1217-01-052)	66mm 100 series (1217-01-066)
Insert Thickness	0.2818 in (7.16 mm) Theoretically at dome	0.2719 in (6.90 mm) Theoretically at dome
Specimen #	4 each	4 each
Comments	1. Choose insert thickness similar for two groups 2. Pick high diametrical clearance for worst case scenario	

Table 2. The Test Matrix and Assigned Test Stations

Group ID	Head		Insert		Diametrical Clearance (μm)	Station ID
	Head ID	Lot #	Insert ID	Lot #		
A. Small (28 mm)	M27-H01	1993817	M27-L01	XUA-62	60.45	1
	M27-H02	2048501	M27-L02	XUD-28	65.28	3
	M27-H03	2048501	M27-L03	XNK-75	71.12	5
	M27-H04	2048501	M27-L04	XRB-44	65.02	7
B. Large (44 mm)	M27-BH01	2088190	M27-BL01	4195614	90.17	2
	M27-BH02	2088190	M27-BL02	4195614	94.49	4
	M27-BH03	2088190	M27-BL03	4195614	104.39	6
	M27-BH04	2088190	M27-BL04	4195614	87.88	8

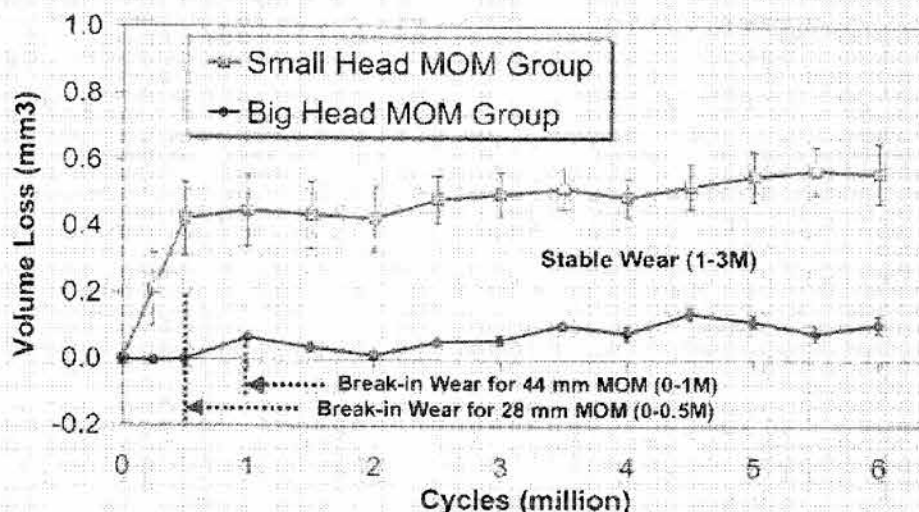
Results and Discussion

In general, the wear results for the small head group consisted of a rapid break-in period (0-0.5MC) and a stabilized period (1-6MC, Figure 1), which were consistent with the trends in previous studies [3-5]. The break-in period for the large head group was longer than 0.5MC and was chosen at the first million

cycles based on the total volume loss data (Figure 1). However, the wear for the large head group was low and appeared to be linear over the six million cycles, suggesting the large head with tight clearance control reached stable wear without the break-in period. During 2.5 to 3 million cycles, there was one pair of 28 mm specimens that ran dry due to serum leakage. The test was resumed with replenished serum for the failed station but the data from the failed station was excluded from the analysis.

The total volumetric wear over 6 million cycles were $0.56 \pm 0.12 \text{ mm}^3$ and $0.11 \pm 0.02 \text{ mm}^3$ for the small head group and large head group, respectively (Figure 1). The results showed an 80% wear reduction for the large head group compared to the small head group over the six-million test cycles.

Fig.1 The Accumulated Volume Loss (Combined Wear)



The wear rates during the break-in period were $0.85 \pm 0.36 \text{ mm}^3/\text{MC}$ (0-0.5MC) and $0.07 \pm 0.02 \text{ mm}^3/\text{MC}$ (0-1MC) for the small head and large head group, respectively; suggesting a wear reduction of 92%. The stabilized wear (1-6MC) was comparable between two groups, about $0.03 \pm 0.04 \text{ mm}^3/\text{MC}$ and $0.02 \pm 0.00 \text{ mm}^3/\text{MC}$ for small and large head group, respectively (Figure 2).

For the large head group, the fact that overall wear rate was similar to the stabilized wear rate ($0.02 \text{ mm}^3/\text{MC}$) suggested that the large head metal-on-metal skipped the break-in period and achieved stable wear directly.

The diametrical clearance for each couple remained similar before and after the wear test (Table 3). For the small head group, the clearance changed

from $65.5 \pm 4.4 \mu\text{m}$ to $62.9 \pm 6.2 \mu\text{m}$. For the large head group, the diametrical clearance changed from $94.2 \pm 7.3 \mu\text{m}$ to $91.8 \pm 8.2 \mu\text{m}$.

Fig.2 The Wear Rate at Different Stage of the Test

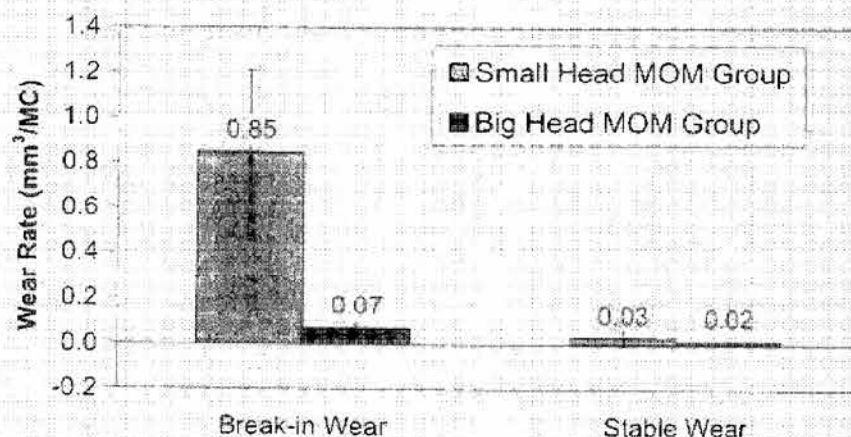


Table 3. Diametrical Clearance Before and After the Wear Test

Group ID	Head ID	Insert ID	Diametrical Clearance (μm)	
			Pre-test	Post-Test
A. Small (28 mm)	M27-H01	M27-L01	60.45	57.66
	M27-H02	M27-L02	65.28	63.50
	M27-H03	M27-L03	71.12	71.37
	M27-H04	M27-L04	65.02	58.93
B. Large (44 mm)	M27-BH01	M27-BL01	90.17	85.85
	M27-BH02	M27-BL02	94.49	90.93
	M27-BH03	M27-BL03	104.39	103.63
	M27-BH04	M27-BL04	87.88	86.61

The surface roughness of the 28 mm heads increased from 0.0076 ± 0.0008 inches to 0.0095 ± 0.0026 inches before and after the test, respectively. For the 44 mm heads, the surface roughness increased from 0.0067 ± 0.0007 inches to 0.0113 ± 0.0029 inches before and after the test, respectively. The surface roughness of the 28 mm inserts increased from 0.0074 ± 0.0019 inches to 0.0118 ± 0.0106 inches before and after the test, respectively. For the 44 mm

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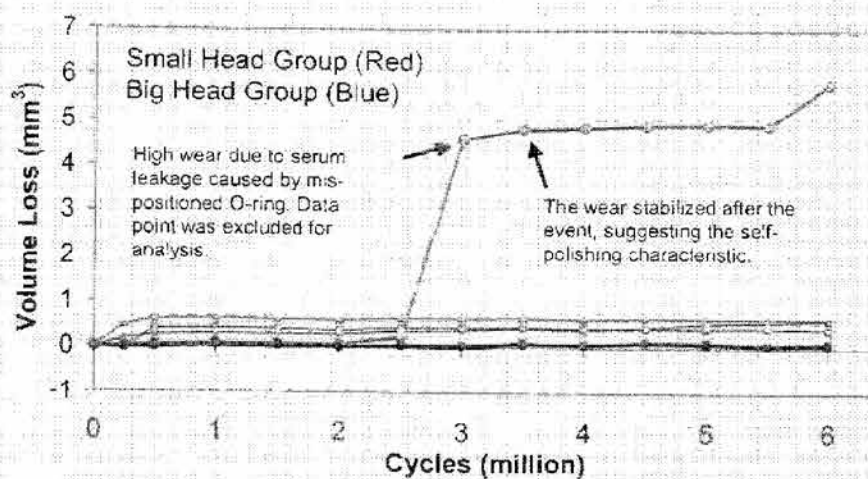
inserts, the surface roughness increased from 0.0108 ± 0.0027 inches to 0.0184 ± 0.0072 inches before and after the test, respectively (Table 4).

Table 4. Surface Roughness Before and After the Wear Test

Group	Station ID	Head Ra (inch)			Insert Ra (inch)		
		Head ID	Pre-Test	Post-Test	Insert ID	Pre-Test	Post-Test
A. Small (28 mm)	1	M27-H01	0.0087	0.0121	M27-L01	0.0092	0.0031
	3	M27-H02	0.0076	0.0070	M27-L02	0.0086	0.0262
	5	M27-H03	0.0069	0.0114	M27-L03	0.0052	0.0046
	7	M27-H04	0.0071	0.0076	M27-L04	0.0065	0.0131
B. Large (44 mm)	2	M27-BH01	0.0059	0.0074	M27-BL01	0.0098	0.0117
	4	M27-BH02	0.0073	0.0133	M27-BL02	0.0139	0.0184
	6	M27-BH03	0.0062	0.0106	M27-BL03	0.0075	0.0284
	8	M27-BH04	0.0073	0.0138	M27-BL04	0.0118	0.0151

On the station that ran dry, the test specimens experienced high wear and roughened bearing surfaces. A new stabilized state, however, was reached after another half-million test cycles, suggesting a "self-polishing" characteristic of the metal-on-metal bearings (Figure 3).

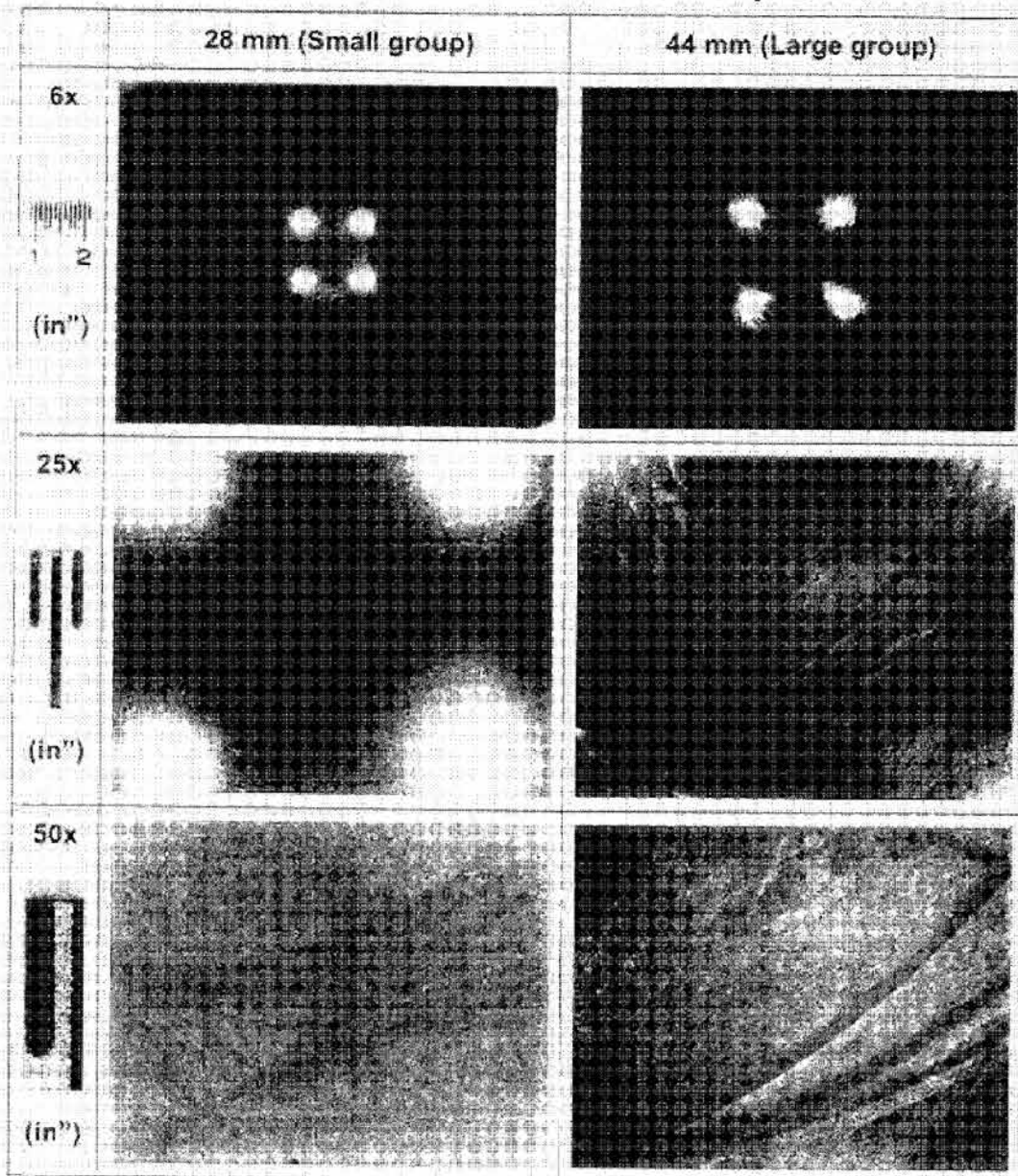
Fig.3 The Wear Rate at Different Stage of the Test



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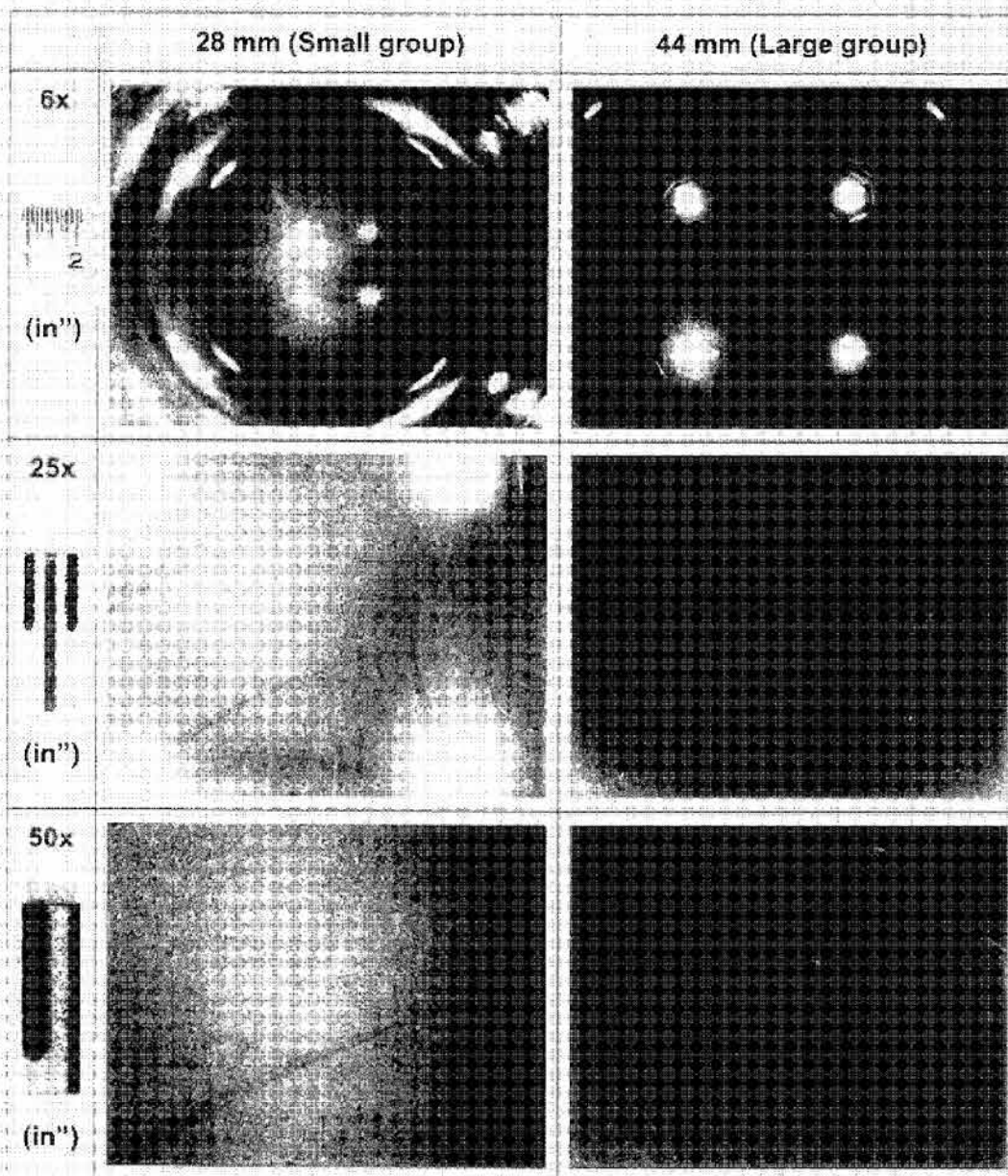
The surfaces of the heads and inserts appeared to be roughened at the articulating area with fine scratches. Typical surface observations for the test specimens are provided in Figure 4 and Figure 5. The whitened articulating area noted in these figures is due to light reflection.

Fig.4 Typical Head Surfaces After 6-million Cycles Test



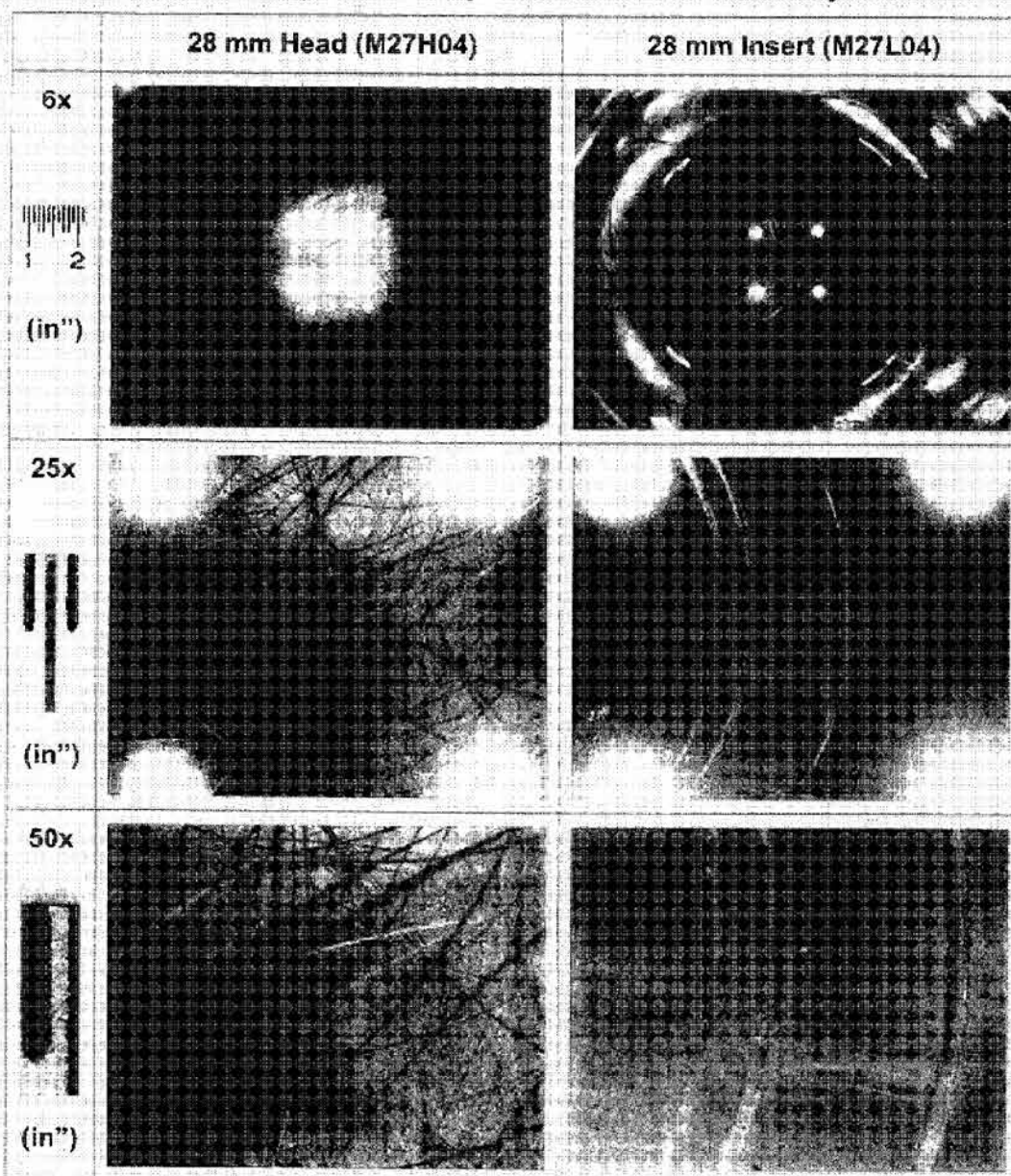
The curved scratches may be created due to 3rd body particles that were driven by the motion of the test stations. These particles may come from the CoCrMo wear debris of the heads and inserts, which are very hard materials and stayed in the wear interfaces due to the inverted setup of the wear test.

Fig.5 Typical Insert Surfaces After 6-million Cycles Test



On the station that ran dry, the test specimens (M27H04 and M27L04) experienced another increased wear from 5.5 to 6-million cycles. The surface had deep and circular scratches, which was due to 3rd body wear. The particle may be trapped at the bearing interface and created gauging lines with the motion of the test station (Figure 6).

Fig.6 The High Wear Couple at the End of 6-million Cycles



Conclusion

The modern large size metal-on-metal total hip prostheses (44 mm) provided substantial wear reduction compared to the small size (28 mm). The current study demonstrated an 80% overall wear reduction over the six-million cycles test, and, a 92% of wear reduction during the break-in period. This is clinically significant in that reducing the wear rate reduces metal ion release and potentially reduces osteolysis associated with wear of total hip arthroplasty [2].

References

- [1] Dobbs, H. S. (1980). "Survivorship of total hip replacements." J Bone Joint Surg 62B: 168-173.
- [2] Liao, Y.-S. and M. Hanes (2006). The Relationship of Metal-on-Metal Wear and Metal Ion Release in the Serum Lubricant. Orthopaedic Research Society, Chicago, IL.
- [3] Dowson, D., C. Hardaker, et al. (2004). "A hip joint simulator study of the performance of metal-on-metal joints: Part II: design." J Arthroplasty. 19(8 Suppl 3): 124-30.
- [4] Chan, F., J. Bobyn, et al. (1999). "The Otto Aufranc Award - Wear and lubrication of metal-on-metal hip." Clin Orthop Relat Res 369: 10-24.
- [5] Liao, Y.-S., J. C. Fryman, et al. (2004). Effects of Clearance, Head Size and Start-Stop Protocol on Wear of Metal-on-Metal Hip Joint Bearings in a Physiological Anatomical Hip Joint Simulator. Orthopaedic Research Society, San Francisco, CA.

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0000063

PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

DEPUY022771692

EXHIBIT VI

Clearance Letters for Predicate Devices

0000064



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Lynette Whitaker, RAC
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
P.O. Box 988
Warsaw, Indiana 46581-0988

Re: K003523

Trade Name: Pinnacle 36mm Metal-on-Metal Acetabular Cup Liners

Regulatory Class: III

Product Code: KWA

Dated: November 13, 2000

Received: November 15, 2000

Dear Ms. Whitaker:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

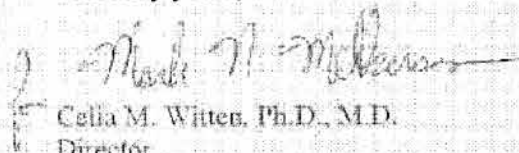
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

0000065

Page 2 - Ms. Lynetter Whitaker, RAC

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

0000066



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 13 2000

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Cheryl K. Hastings
Director, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988



Re: K002883

Trade Name: Pinnacle Metal-On-Metal Acetabular Cup Liners

Regulatory Class: III

Product Codes: JDM and KWA

Dated: September 13, 2000

Received: September 15, 2000

Dear Ms. Hastings:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general control provisions of the Act. The general control provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

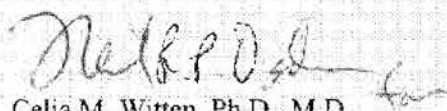
This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

0000067

Page 2 - Ms. Cheryl K. Hastings

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative and
Neurological Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

0000068



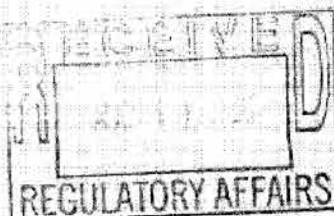
DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 5 - 2005

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Natalie Heck
Manager, Regulatory Affairs
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988



Re: K040627

Trade/Device Name: DePuy ASR™ Modular Acetabular Cup System

Regulation Number: 21 CFR 888.3330

Regulation Name: Hip joint metal/metal semi-constrained, with an uncemented acetabular component, prosthesis

Regulatory Class: III

Product Code: KWA

Dated: May 23, 2005

Received: May 24, 2005

Dear Ms. Heck:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

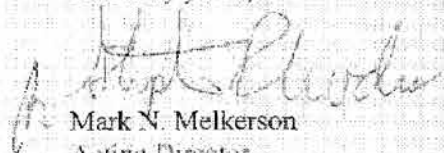
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Page 2 – Ms. Natalie Heck

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0210. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,


Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

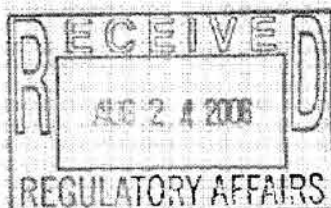
Enclosure

0000070

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

August 21, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Received: 18-AUG-2006
Product: DEPUY PINNACLE
User Fee ID Number: 6027007AL
ACETABULAR CUP
LINERS

The Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier(e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
P.O. Box 956733
St. Louis, MO 63195-6733.

U.S. Bank
956733
1005 Convention Plaza
St. Louis, MO 63101
(314) 418-4983

The check should be made out to the Food and Drug Administration referencing the payment identification number, and a copy of the User Fee Cover sheet should be included with the check. A copy of the Medical Device User Fee Cover Sheet should be faxed to CDRH at (301) 594-2977 referencing the 510(k) number if you have not already sent it in with your 510(k) submission. After the FDA has been notified of the receipt of your user fee payment, your 510(k) will be filed and the review will begin. If payment has not been received within 30 days, your 510(k) will be deleted from the system. Additional information on user fees and how to submit your user fee payment may be found at www.fda.gov/oc/mdufma.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510(k) Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800)638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,



Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

08/22/06 TUE 10:58 FAX 3015942977

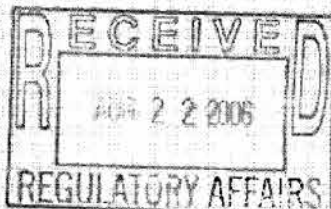
FDA CDRH ODE POS

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

August 21, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Received: 18-AUG-2006
Product: DEPUY PINNACLE
User Fee ID Number: 6027007AL
ACETABULAR CUP
LINERS

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The Act, as amended by the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250), specifies that a submission shall be considered incomplete and shall not be accepted for filing until fees have been paid (Section 738(f)). Our records indicate that you have not submitted the user fee payment information and therefore your 510(k) cannot be filed and has been placed on hold. Please send a check to one of the addresses listed below:

By Regular Mail

By Private Courier(e.g., Fed Ex, UPS, etc.)

Food and Drug Administration
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1005 Convention Plaza
St. Louis, MO 63101
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08/22/06 TUE 10:58 FAX 3015942977

FDA CDRH ODE POS

002

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, or HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/electsub.html.

Please note that since your 510(k) has not been reviewed, additional information may be required during the review process and the file may be placed on hold once again. If you are unsure as to whether or not you need to file a 510k Submission with FDA or what type of submission to submit, you should first telephone the Division of Small Manufacturers, International and Consumer Assistance (DSMICA), for guidance at (240) 276-3150 or its toll-free number (800) 638-2041, or contact them at their Internet address www.fda.gov/cdrh/dsma/dsmastaf.html, or you may submit a 513(g) request for information regarding classification to the Document Mail Center at the address above. If you have any questions concerning receipt of your payment, please contact Christina Zeender at 301-827-2860. If you have questions regarding the status of your 510(k) Submission, please contact DSMICA at the numbers or address above.

Sincerely yours,

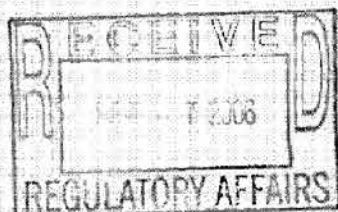
Marjorie Shulman

Marjorie Shulman
Consumer Safety Officer
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 05, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Received: 01-SEP-2006
Product: DEPUY PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

The Food and Drug Administration (FDA), Center for Devices and Radiological Health (CDRH), has received the Premarket Notification, (510(k)), you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product and for the above referenced 510(k) submitter. Please note, if the 510(k) submitter is incorrect, please notify the 510(k) Staff immediately. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in all future correspondence that relates to this submission. We will notify you when the processing of your 510(k) has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official 510(k) submission.

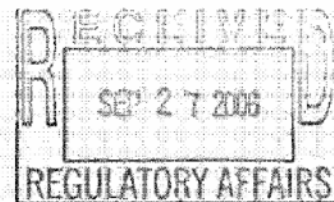
Please note the following documents as they relate to 510(k) review: 1) Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act (MDUFMA). Please review this document at www.fda.gov/cdrh/mdufma/guidance/1219.html. 2) Guidance for Industry and FDA Staff entitled, "Format for Traditional and Abbreviated 510(k)s". This guidance can be found at www.fda.gov/cdrh/ode/guidance/1567.html. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k). 3) Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

In all future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's e-Copy Program, you may replace one paper copy of an premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please visit our web site at www.fda.gov/cdrh/elecsb.html.

Lastly, you should be familiar with the regulatory requirements for medical devices available at Device Advice www.fda.gov/cdrh/devadvice/. If you have questions on the status of your submission, please contact DSMICA at (240) 276-3150 or the toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsma/dsmastaf.html>. If you have policy or procedural questions, please contact anyone on the 510(k) Staff at (301)594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Office of Device Evaluation
Center for Devices and Radiological Health



Dear Ms. Schuler,

Thank you for permission of this email (provided in your cover letter). To complete our review of your Special 510(k), DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners, K062426, we will need to place your document on hold until we receive the information presented below. Please send in your response in duplicate to the Document Mail Center via standard mail. If you need to contact me, please email me at julie.gantenberg@fda.hhs.gov.

PLEASE EMAIL ME TO VERIFY RECEIPT OF THIS REQUEST.

1. Although you provided device description information, the narrative and mechanical drawings do not appear to provide complete information. Therefore, in order to better understand your device system, please provide the information below.
 - a. Please provide computer aided drawings (CAD) of the subject metal-on-metal (MOM) liners compared to a legally marketed MOM liner showing wall thicknesses at the dome, 45 degrees, and rim of the liner.
 - b. Regarding the subject 40mm and 44mm MOM liners on p.16, you provided the minimum/maximum diametrical clearance between the head and the liners. The minimum to maximum clearance range provided was 80 - 120 microns for each liner and predicate. We calculated the minimum and maximum clearance ranges for a representative 40mm liner/head combination. We used the 40mm liner ID = 1.577 ± 0.001 in. (dimension per EGR drawing #DWG-121887456 in subject 510(k)) with a 40mm M-Spec head with -2.0 neck offset i.e. Head $\varnothing = 1.5748 \pm 0.0004$ in. (dimension per K060031 for the 12/14 Articuleze M Head, 40mm -2.0 neck offset - drawing #1365C4C00). For this particular combination, we calculated a clearance range of $20.32\mu\text{m} - 91.44\mu\text{m}$ which is different from what you provided. Therefore, please explain exactly how the included clearance ranges were calculated for each subject liner. Please also note that the subject 36mm liner MOM liner was not included in your table on p.16. Therefore, for each subject size and design of femoral head/liner couple, please provide a detailed analysis on how the clearance range was calculated identifying the specific liner inner diameters and head diameters used. Please provide a table indicating the nominal clearance +/- the standard deviation in addition to the minimum and maximum clearance ranges for each femoral head/liner couple. Please resubmit all supporting, head engineering drawings used in the analysis in your response.
 - c. Regarding your compatible components, you have provided a list of femoral heads and acetabular shells in Exhibit III. You stated that the K060031 M-Spec CoCrMo heads were previously cleared for use with polyethylene liners but are to be used with the subject 40mm and 44mm MOM liners. It is not clear what exactly the M-Spec finish entails or if the M-Spec heads have been cleared in a MOM system previously. Please note that you did not provide a list of femoral stems to be used with the subject system. Additionally, you did not provide a rationale as to why the components not originally cleared for use in a MOM system will not affect the clinical performance of your device as compared to that of the original clinical data. Therefore, please address the issues below.
 - (1). Please provide more information on the M-Spec finish used for the 40mm and 44mm heads and how this material relates to the articulating materials studied originally in your clinical data. Please indicate (with 510(k) numbers) if the M-Spec finish has been cleared previously for use with your MOM system.
 - (2). The DePuy Femoral Head table on p.32 lists compatible M Spec head sizes for the subject liners as "40-44mm." Please provide revised table modified to correspond with the device description i.e. 40mm and 44mm.
 - (3). Please provide a list of femoral stems along with their product codes cleared that are to be used with the subject liners. This information is necessary because FDA reviews and clears systems (e.g. cup, insert, head, and stem) and not individual components.

K062426 - Page 2 of 3

- (4). Please provide a rationale for using the proposed acetabular shells and stems as part of your Pinnacle MOM system. Be sure to address why differences in design will not affect the clinical performance of your device (third body wear of hydroxylapatite particulate, etc.)
2. Although you provided a Design Control Activities Summary on p. 20, more information is needed to better understand the verification activities performed. Also, you did not identify the method used to determine the risks. Therefore, please address the issues below. Please provide a revised Design Control Activities Summary if appropriate.
- a. Please identify the method used to determine the risks.
- b. Regarding your 40mm and 44mm liners, your verification activities included a wear testing comparison for 44mm and 28mm bearing couples. More information is needed regarding this verification activity. Please address the issues below.
- (1). Your wear testing should be representative of the worst-case subject components in terms of head size and clearance when considering the clearance range provided in your item 1b response. Either provide a detailed justification for the device components and test conditions selected as being worst case or perform additional wear verification activities on a worst case scenario. Should you provide a rationale supporting worst case components and clearances already tested, please address the issues below.
- i. Please provide a detailed rationale how the subject liner/head couples and clearances chosen represent a worst case scenario based on the minimum and maximum clearance values provided in your item 1b response. Your rationale should discuss, but not be limited to, how your minimum clearance is not too small that it would cause clamping or seizing to occur during the articulation.
- ii. For the test report provided in Exhibit V, the part number i.e. 1365-69-000 identified for the 44mm head does not appear to match that identified for the 44mm head in K060031. Part number 1365-69-000 appears to correspond to a 48mm head size in K060031(?). Please clarify this apparent discrepancy.
- iii. Please elaborate if the wear patterns resulting from the test performed on the 44mm bearing couples showed typical and expected wear patterns that are substantially equivalent to those on legally marketed MOM predicates.
- (2). Regarding your flexion/extension frictional torque verification activity, this activity was performed in support of the K040627 ASR modular predicate which was manufactured from cast CoCrMo (ASTM F75). Although the study tested different bearing materials and sizes, the study only used a sample size of one for each bearing couple tested and the subject 44 M-Spec head/liner couple was not tested. It is unclear how the results of this verification activity support the clearances provided in your response to item 1b, the M-Spec head/liner material couple or the different shells used with the subject system. Either provide a more detailed justification supporting the subject worst case couple (material, clearances, etc.) or perform additional verification activities demonstrating that the flexion/extension frictional torque values for the subject sizes in a worst case scenario is adequate.
- c. Regarding the subject 36mm liner with the reduced outer diameter, your verification activity included only a deformation test. More information is needed on this deformation test. In addition, we believe that the additional verification activities regarding the retention mechanism between the liner and the subject shells is necessary. Please address the issues below.
- (1). Please provide the test report for the Deformation verification activity performed.

K062426 - Page 3 of 3

- (2). Please address the retention mechanism i.e. the strength of the liner/shell locking mechanism between the subject liner and the subject shells. We believe that your verification activities should include push-out in addition to either torque-out and/or lever-out verification activities.
3. In your Indications for Use enclosure, the underlined sentence states, "The Pinnacle Metal-On-Metal Acetabular cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only." The heads for which you are listing as being compatible also include the 36mm S-ROM femoral heads and the 36mm Articul/eze femoral heads. It is not clear if these additional heads include the M-Spec finish. You also listed the Standard Profile Shells and the Deep Profile shells as being compatible. For these shells, it is not clear if they are part of the Pinnacle line. Therefore, please revise your Indications for Use enclosure by modifying the underlined sentence to accurately reflect the compatible components or provide clarification to the underlined sentence. Should you modify your Indications for Use enclosure, please provide a modified 510(k) Summary of Safety and Effectiveness reflecting your response.
4. You provided a package insert in Exhibit IV. According to 21 CFR part 801, adequate instructions for use are required for this device. Although you state on p.50 that the "Pinnacle Acetabular cup Inserts can be used only with Pinnacle Acetabular shells," please note that the indications for use should match those in your Indications for Use enclosure. Please refer to item #3 regarding the underlined sentence and reflect the Indications for Use as per your response for item #3.

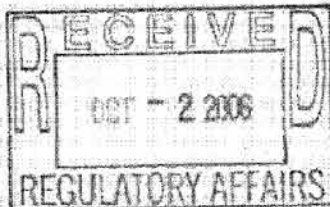
Depending on your response, additional preclinical and/or clinical data may be needed. Please email me if you have any questions. We look forward to receiving your response soon.

Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
FDA Reviewer for DGRND/OJDB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

September 27, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 512(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,



Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k): Premarket Notification

October 5, 2006

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Attn: Ms. Gantenberg



DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (574) 267 8143

Re: Request for Additional Information - K062426 DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners

Dear Ms. Gantenberg

DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate as an addendum to the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners K062426, currently under review by FDA. This submission is made to comply with the request for additional information made by e-mail on September 26, 2006

Pursuant to 21 CFR 807.95(c) (3), DePuy considers our intent to market this device and this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

DePuy Orthopaedics acknowledges that the introduction of this device into domestic commercial distribution will be contingent upon written clearance of the 510(k) by the Food and Drug Administration.

Thank you in advance for your consideration of our application. If there are any further questions regarding this submission, please feel free to contact me via phone (574) 372-7469, fax (574) 371-4987, or email at aschuler@dpyus.jnj.com.

Regards,

A handwritten signature in cursive script, appearing to read "Anne M. Schuler".

Anne M. Schuler
Sr Regulatory Affairs Associate
DePuy Orthopaedics, Inc.

0000001

**Addendum to DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners 510(K), K062426
Request for Additional Information, September 26, 2006**

Question 1. Although you provided device description information, the narrative and mechanical drawings do not appear to provide complete information. Therefore, in order to better understand your device system, please provide the information below.

- a. Please provide computer aided drawings (CAD) of the subject metal-on-metal (MOM) liners compared to a legally marketed MOM liner showing wall thicknesses at the dome, 45 degrees, and rim of the liner.

CAD drawings of each of the subject liners and a legally marketed MOM liner (Pinnacle liner size 36mm x 52mm, drawing number 121887352, cleared in K003523) are provided in Exhibit 1. All liners shown have the thickness at the dome, at 45 degrees from the dome and at the rim of the liner. Sizes and product numbers are clearly identified below each liner.

- b. Regarding the subject 40mm and 44mm MOM liners on p.16, you provided the minimum/maximum diametrical clearance between the head and the liners. The minimum to maximum clearance range provided was 80 - 120 microns for each liner and predicate. We calculated the minimum and maximum clearance ranges for a representative 40mm liner/head combination. We used the 40mm liner ID = 1.577 ± 0.001 in. (dimension per EGR drawing #DWG-121887456 in subject 510(k)) with a 40mm M-Spec head with -2.0 neck offset i.e. Head $\phi = 1.5748 \pm 0.0004$ in. (dimension per K060031 for the 12/14 Articulate M Head, 40mm -2.0 neck offset - drawing #1365C4C00). For this particular combination, we calculated a clearance range of 20.32 μ m - 91.44 μ m which is different from what you provided. Therefore, please explain exactly how the included clearance ranges were calculated for each subject liner. Please also note that the subject 36mm liner MOM liner was not included in your table on p.16. Therefore, for each subject size and design of femoral head/liner couple, please provide a detailed analysis on how the clearance range was calculated identifying the specific liner inner diameters and head diameters used. Please provide a table indicating the nominal clearance +/- the standard deviation in addition to the minimum and maximum clearance ranges for each femoral head/liner couple. Please resubmit all supporting, head engineering drawings used in the analysis in your response.

A detailed dimensional analysis containing the following information is provided in Exhibit 2:

- A list of subject liners and femoral heads used for the analysis
- A table with the nominal dimensions, tolerances, and minimum and maximum for all liner and head sizes (DePuy does not use standard deviation tolerancing)
- Calculations
- Radial and Diametrical clearances
- Diametrical clearances in inches, millimeters and micrometers (μ m values were rounded when reported in K062426)

Also provided in Exhibit 2 are engineering drawings for the femoral heads used in the analysis.

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- c. Regarding your compatible components, you have provided a list of femoral heads and acetabular shells in Exhibit III. You stated that the K060031 M-Spec CoCrMo heads were previously cleared for use with polyethylene liners but are to be used with the subject 40mm and 44mm MOM liners. It is not clear what exactly the M-Spec finish entails or if the M-Spec heads have been cleared in a MOM system previously. Please note that you did not provide a list of femoral stems to be used with the subject system. Additionally, you did not provide a rationale as to why the components not originally cleared for use in a MOM system will not affect the clinical performance of your device as compared to that of the original clinical data. Therefore, please address the issues below.

- (1). Please provide more information on the M-Spec finish used for the 40mm and 44mm heads and how this material relates to the articulating materials studied originally in your clinical data. Please indicate (with 510(k) numbers) if the M-Spec finish has been cleared previously for use with your MOM system.

M-Spec heads are Co-Cr-Mo heads that are manufactured to tighter engineering specifications in order to provide an optimal fit for metal-on-metal applications. Standard Co-Cr-Mo heads have a sphericity requirement of 0.00075 inches. M-Spec heads have a sphericity requirement of 0.000197 inches which is a tighter specification. The S-ROM M-Spec heads were cleared through internal documentation to the 510k in which the S-ROM heads (K851422) were originally cleared and the M-Spec Articuleze heads were cleared through internal documentation to the 510k in which the Articuleze heads (K980513) were originally cleared. Both the S-ROM M-Spec and Articuleze M-Spec heads were cleared for use in the Pinnacle MOM system in K003523.

- (2). The DePuy Femoral Head table on p.32 lists compatible M Spec head sizes for the subject liners as "40-44mm." Please provide revised table modified to correspond with the device description i.e. 40mm and 44mm.

The table listing the compatible M Spec heads has been revised to clarify the head sizes. The revised table is provided in Exhibit 3.

- (3). Please provide a list of femoral stems along with their product codes cleared that are to be used with the subject liners. This information is necessary because FDA reviews and clears systems (e.g. cup, insert, head, and stem) and not individual components.

A list of compatible femoral stems available for the Pinnacle MOM Acetabular System is provided in Exhibit 3. The stem families listed were cleared for use with MOM heads and liners in K040627.

- (4). Please provide a rationale for using the proposed acetabular shells and stems as part of your Pinnacle MOM system. Be sure to address why differences in design will not affect the clinical performance of your device (third body wear of hydroxylapatite particulate, etc.)

The Pinnacle 100 Series, 300 series and Sector shells have been previously cleared for use in the Pinnacle MOM system in K003523. The Pinnacle HA Sector and Pinnacle HA 100 Series shells (cleared in K031495) have the same design as those cleared in K003523 with an additional hydroxylapatite (HA) coating. The HA coating is the same coating that is used on the predicate ASR acetabular cups used in the ASR MOM system cleared in K040627. The concerns associated with wear and fixation in a MOM system due to the presence of HA coating or particulates were addressed and cleared in K040627.

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The Pinnacle Multi-hole, Standard and Deep Profile Shells have all been previously cleared for use with polyethylene liners. The Pinnacle Multi-hole Shells were cleared through internal documentation to K000306. The Pinnacle Standard and Deep Profile Shells were cleared in K033338. The interface and locking mechanism between these shells and the subject Pinnacle MOM liners are identical to those in the Pinnacle 100, 300 and Sector shells that have been previously cleared for use in the Pinnacle MOM System. The only differences between these shells and the shells previously cleared for MOM indications are: the Multi-hole shell has additional holes in the dome area, the Standard Profile shell has additional screw holes in the dome area, increased wall thickness and added peripheral screw holes and the Deep Profile shells have additional screw holes in the dome area, increased wall thickness, added peripheral screw holes and an added countersink feature to the outer end of the dome screw holes. These differences would not be expected to affect the safety or efficacy of the shells when used with MOM liners.

The compatible femoral stems listed in Exhibit 3 were previously cleared for use with MOM heads and liners in K040627.

Question 2. Although you provided a Design Control Activities Summary on p. 20, more information is needed to better understand the verification activities performed. Also, you did not identify the method used to determine the risks. Therefore, please address the issues below. Please provide a revised Design Control Activities Summary if appropriate.

a. Please identify the method used to determine the risks.

A DFMEA (Design Failure Mode and Effects Analysis) was used to determine risks associated with this product.

b. Regarding your 40mm and 44mm liners, your verification activities included a wear testing comparison for 44mm and 28mm bearing couples. More information is needed regarding this verification activity. Please address the issues below.

(1). Your wear testing should be representative of the worst-case subject components in terms of head size and clearance when considering the clearance range provided in your item 1b response. Either provide a detailed justification for the device components and test conditions selected as being worst case or perform additional wear verification activities on a worst case scenario. Should you provide a rationale supporting worst case components and clearances already tested, please address the issues below.

i. Please provide a detailed rationale how the subject liner/head couples and clearances chosen represent a worst case scenario based on the minimum and maximum clearance values provided in your item 1b response. Your rationale should discuss, but not be limited to, how your minimum clearance is not too small that it would cause clamping or seizing to occur during the articulation.

It is recognized that the key to achieving optimal wear performance from MOM hip bearing is the establishment of a full fluid film lubrication, a condition known as elastohydrodynamic lubrication (EHL).¹ Under EHL conditions the fluid film effectively separates the bearing surfaces greatly reducing or eliminating the direct metal-to-metal contact that causes adhesive wear of the bearing surfaces. A factor that affects the fluid film thickness is the bearing diameter. Larger bearing diameters result in greater relative velocity between bearing surfaces which promotes thicker

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fluid films. In addition, the diametrical clearance of the bearing surfaces also has a direct effect on the fluid film thickness, the smaller the clearance the thinner the fluid film. Therefore, the predicate Pinnacle 28 mm head/liner combination used as the control in the simulated wear study (WR # 060177) represented the worst-case combination because it has the smallest bearing diameter and the smallest diametrical clearances (40 μ m min. and 80 μ m max.) in the Pinnacle system. Testing the subject 44 mm liner was not intended to represent the worst-case scenario rather to confirm the expected trend toward lower wear at higher bearing diameters.

Seizing or clamping of the head during articulation occurs when the head/liner clearances aren't adequate. Therefore, as above, the predicate Pinnacle 28mm head/liner combination would be considered worst case since it has smaller diametrical clearances than the subject combinations. Wear testing confirmed that neither the worst case 28mm head/liner nor the subject 44mm head/liner experienced seizing or clamping. Since neither of these sizes cause clamping or seizing to occur, they would also not be expected to occur in intermediate sizes.

- ii. **For the test report provided in Exhibit V, the part number i.e. 1365-69-000 identified for the 44mm head does not appear to match that identified for the 44mm head in K060031. Part number 1365-69-000 appears to correspond to a 48mm head size in K060031(?). Please clarify this apparent discrepancy.**

The 44mm head part number, 1365-69-000, listed in the test report in Exhibit V was incorrectly reported. The report has been revised to list the correct 44mm part number, 1365-62-000. A revised report is provided in Exhibit 4.

- iii. **Please elaborate if the wear patterns resulting from the test performed on the 44mm bearing couples showed typical and expected wear patterns that are substantially equivalent to those on legally marketed MOM predicates.**

In simulator wear studies conducted using MOM head/liner combinations, previous testing has shown that it is typical to see a run-in wear period followed by steady-state wear that continues for the rest of the cycles. The higher run-in wear period usually takes place over the first 0.5 million cycles or less and is indicative of the metal head wearing into the insert, breaking down any high points in the microstructure and actually creating a 'bed' for itself in the liner. Once equilibrium is reached the wear decreases to a near immeasurable point. The wear patterns produced by the 44mm subject liner in the wear study reported in this 510k followed this pattern of an initial run-in period followed by a steady-state of wear. The previously cleared 28 mm head/ liner control also showed this same type of wear. In addition, this same wear pattern was seen in simulator wear testing conducted for the previously cleared (K003523) predicate Pinnacle 36 mm liner and in testing conducting for the previously cleared (K040627) predicate ASR MOM system.

Figure 4 and Figure 5 in the Wear Study (WR #060177) provided in Exhibit 5 of the original submission on pages 59 and 60 show the wear patterns of the 28 mm and 44 mm heads and liners after 6 million cycles. Both the bearing combinations showed slightly roughened surfaces with fine scratches at the articulating areas (Table 4, page 58). The fine scratches are most likely caused by wear debris from the bearing surfaces during testing. These wear patterns were typical for both the predicate 28 mm and subject 44 mm bearing couples.

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- (2). Regarding your flexion/extension frictional torque verification activity, this activity was performed in support of the K040627 ASR modular predicate which was manufactured from cast CoCrMo (ASTM F75). Although the study tested different bearing materials and sizes, the study only used a sample size of one for each bearing couple tested and the subject 44 M-Spec head/liner couple was not tested. It is unclear how the results of this verification activity support the clearances provided in your response to item 1b, the M-Spec head/liner material couple or the different shells used with the subject system. Either provide a more detailed justification supporting the subject worst case couple (material, clearances, etc.) or perform additional verification activities demonstrating that the flexion/extension frictional torque values for the subject sizes in a worst case scenario is adequate.

The flexion/extension frictional torque study that was submitted in K040627 (Additional Information submitted December 2, 2004, page 50) tested the following head/liner combinations: 28mm metal on polyethylene, 36mm metal on metal (unworn), 36mm metal on metal (worn), 55mm metal on metal (unworn, head out of specification), 55mm metal on metal (unworn, within specifications) and 55mm metal on metal (worn). The results showed that smaller prostheses size (head/liner diameter) led to a lower frictional moment.

The worst case (maximum mean frictional moment) was determined to be the 55mm metal on metal (unworn, head out of specification) sample with a mean frictional moment of 7.3 Nm during continuous movement.

For components that were within specification, the worst case was determined to be the 55mm metal on metal (worn, within specifications) sample with a mean frictional moment of -6.9 Nm during start-up.

The worst case for a 36mm metal on metal was the unworn sample during continuous movement, with a mean frictional moment of 4.6Nm.

In comparison, a review of the literature showed that the moments required for initial cup loosening of a variety of press-fit cups ranged from 6.8Nm – 55Nm.

The subject 40 and 44mm metal on metal head/liner combinations have the same diametrical clearances as the 36mm metal on metal and the 55mm metal on metal (within specification) samples. Since the 40mm and 44mm sizes fall in between the 36mm and 55mm sizes that were tested, the frictional torque for the 40mm and 44mm sizes would be expected to fall between the frictional torques found for the 36mm and 55mm sizes and would be expected to be less than the worst case 55mm size.

The bearing inserts of the Pinnacle product construct, either the 40 or 44 mm subject liner contained within the Pinnacle porous coated outer shell, are identical to the ASR in all parameters that could affect bearing performance. Specifically the surface finish, diametrical clearances, and form (sphericity) of the ID and OD bearing surface are identical. Therefore, in accordance with elasto-hydrodynamic lubrication theory discussed in the response to Question 2.b.1.i, the bearing performance of the subject Pinnacle liners will be very similar, if not identical to the predicate ASR.

In addition, based on the following information, we believe that the difference in material between the subject head/liner bearing couple and the ASR bearing couple used in the flexion/extension frictional torque study (wrought CoCrMo vs cast CoCrMo) does not have an affect on the results of the test. ASTM F-75 requires that the carbon content of CoCrMo casting alloy material be within the range of 0% – 0.35%. The DePuy internal raw material specification for the predicate ASR bearing couple specifies a carbon content

K062426 - Page 6 of 8

within the range of 0.25% – 0.28%. Adherence to this internal specification guarantees the device will have a carbon content within the upper one-third of the range required by the ASTM specification. The internal raw material specification for the wrought CoCrMo alloy requires a carbon content in the range of 0.21% – 0.35% also ensuring adherence consistently in the upper one-third of the ASTM specification. This demonstrates that there is not a statistical difference in chemistry between the wrought and cast high carbon material combinations. Based on these carbon content requirements, we feel the results of the flexion/extension frictional torque study conducted using the cast CoCrMo ASR bearing couples can be applied to the Pinnacle subject liner/head bearing couples which fall within the range of sizes tested. Further, studies have shown that where elastohydrodynamic lubrication is in effect, as we believe it is based on wear studies, the minor variations in material chemistry that may exist or differences in raw material fabrication methods (wrought v. cast) of the constituent components will not make a measurable difference in bearing performance.

- c. Regarding the subject 36mm liner with the reduced outer diameter, your verification activity included only a deformation test. More information is needed on this deformation test. In addition, we believe that the additional verification activities regarding the retention mechanism between the liner and the subject shells is necessary. Please address the issues below.

- (1). Please provide the test report for the Deformation verification activity performed.

The test report for the Deformation Test is provided in Exhibit 5.

- (2). Please address the retention mechanism i.e. the strength of the liner/shell locking mechanism between the subject liner and the subject shells. We believe that your verification activities should include push-out in addition to either torque-out and/or lever-out verification activities.

The Pinnacle MOM liner is mechanically locked with the shell via a taper junction. The contact area and taper angle determine how well the insert is held inside the shell. The liner thickness does not affect the strength of the locking mechanism. Push out and torque out tests were both conducted for the predicate 28 mm metal Pinnacle liner cleared in K002883. The testing was not repeated for the larger subject liners because the tapers that lock the liner inside the shell have not changed.

- Question 3.** In your Indications for Use enclosure, the underlined sentence states, "The Pinnacle Metal-On-Metal Acetabular cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only." The heads which you are listing as being compatible also include the 36mm S-ROM femoral heads and the 36mm Articulate femoral heads. It is not clear if these additional heads include the M-Spec finish. You also listed the Standard Profile Shells and the Deep Profile shells as being compatible. For these shells, it is not clear if they are part of the Pinnacle line. Therefore, please revise your Indications for Use enclosure by modifying the underlined sentence to accurately reflect the compatible components or provide clarification to the underlined sentence. Should you modify your Indications for Use enclosure, please provide a modified 510(k) Summary of Safety and Effectiveness reflecting your response.

The 36mm S-ROM and 36mm Articulate heads listed as compatible components are heads that meet the M-Spec specifications. The Standard Profile and Deep Profile shells listed are part of the Pinnacle product line. The compatible component information has been revised to clarify this and is provided in Exhibit 3. The Indications for Use enclosure therefore is correct as stated in the original submission.

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K062426 - Page 7 of 8

Question 4. You provided a package insert in Exhibit IV. According to 21 CFR part 801, adequate instructions for use are required for this device. Although you state on p.50 that the "Pinnacle Acetabular cup Inserts can be used only with Pinnacle Acetabular shells," please note that the indications for use should match those in your Indications for Use enclosure. Please refer to item #3 regarding the underlined sentence and reflect the Indications for Use as per your response for item #3.

The Indications for Use listed in the Instructions for Use (IFU) package insert have been revised to match those in the Indications for Use enclosure in the 510k submission. A draft copy of the revised IFU is provided in Exhibit 6.

000008

K062426 - Page 8 of 8

References

1. Medley, J. B., Bobyn, D. J., Krygier, J. J., Chan, F. W., Tanzer, M., Roter, G. E., "Elastohydrodynamic Lubrication and Wear of Metal-on-Metal Hip Implants", World Tribology Forum in Arthroplasty, Rieker, C., Oberholzer, S., Wyss, U., Eds., 2001 Hans Huber, Bern., p. 3-14.

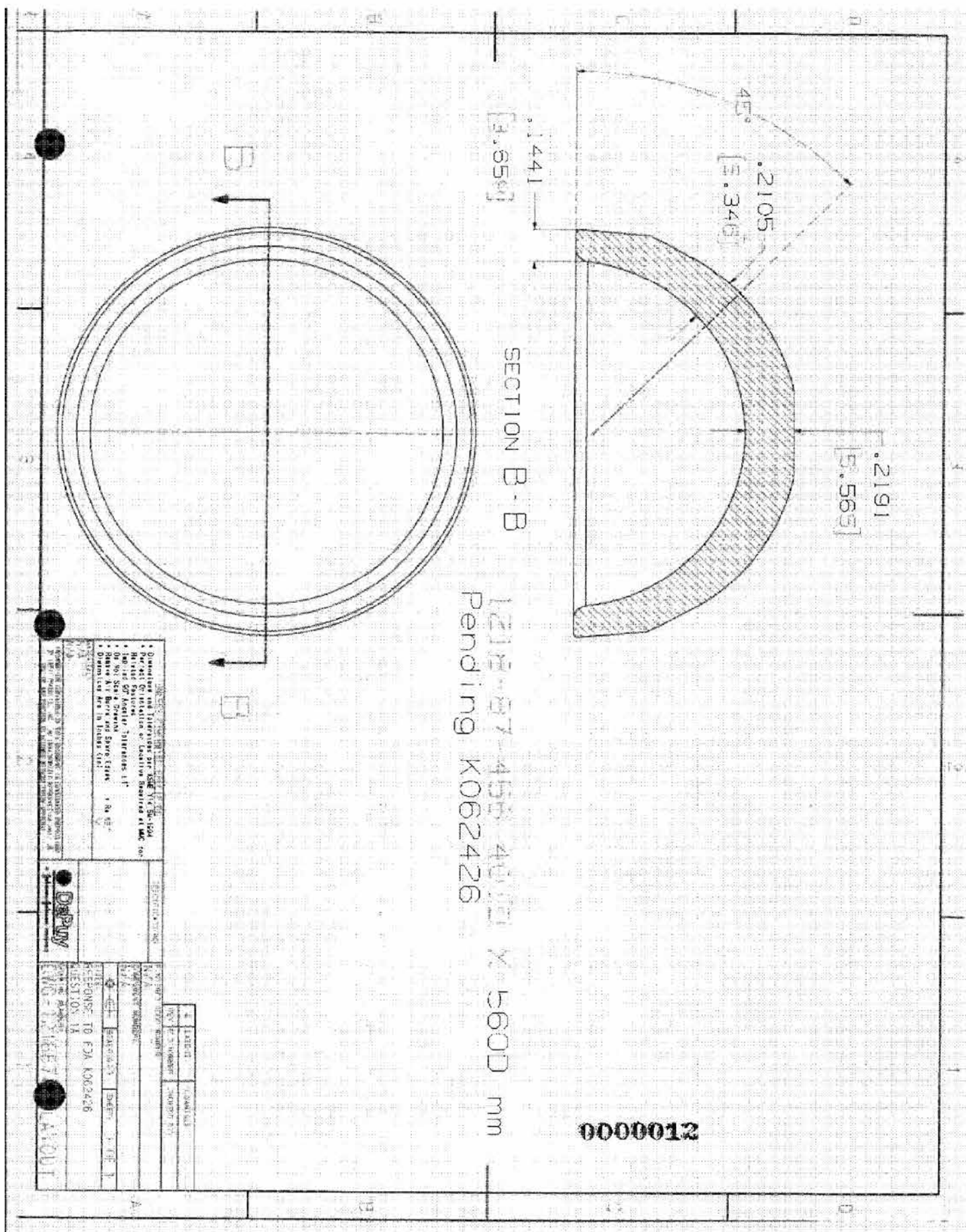
000009

DEPUY022771720

1218-87-350 361D X 500D mm
Pending K062126

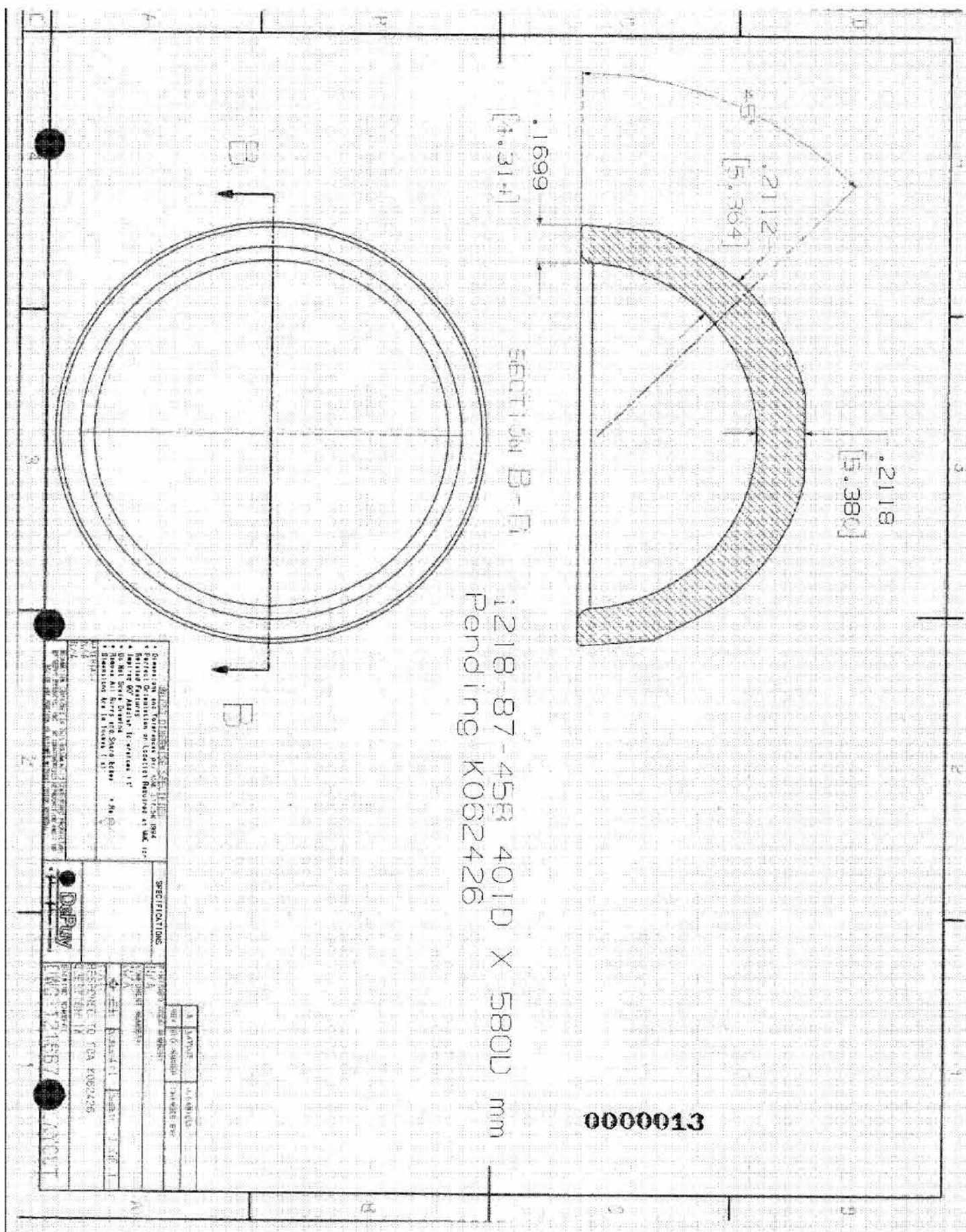
0000011

DEPUY022771721



PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

DEPUY022771722



PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

DEPUY022771723

121E-87-460 401D X 600D mm
Pending K062426

0000014

DEPUY022771725

1218-87-462 441D X 620D mm
Pending K062426

0000016

DEPUY022771726

1218-87-464 441D X 640D mm
Pending K062426

0000017

DEPUY022771727

0000018

DEPUY022771728

DIMENSIONAL ANALYSIS

0000019

PROTECTED DOCUMENT. DOCUMENT SUBJECT TO PROTECTIVE ORDER.

DEPUY022771729

FD-302 (Rev. 11-27-70)

Product Description	Product Number
300-00	12 080 3550
300-01	12 080 3552
400-00	12 080 3558
400-01	12 080 3556
400-02	12 080 3560
1000-0	12 080 3562
1000-1	12 080 3568
1000-2	12 080 3569

The Head Off radius was calculated by dividing the Old diameter on the trip in half. This was necessary for the

This inflation clearance was calculated by subtracting the Head Margin (inches) from the Combined Inflation (inches) to arrive at the Inset Margin on Material Consideration (inches) (10 inches) = INSET MARG - HEAD MARG.

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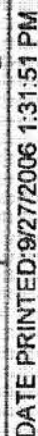
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FEMORAL HEAD DRAWINGS

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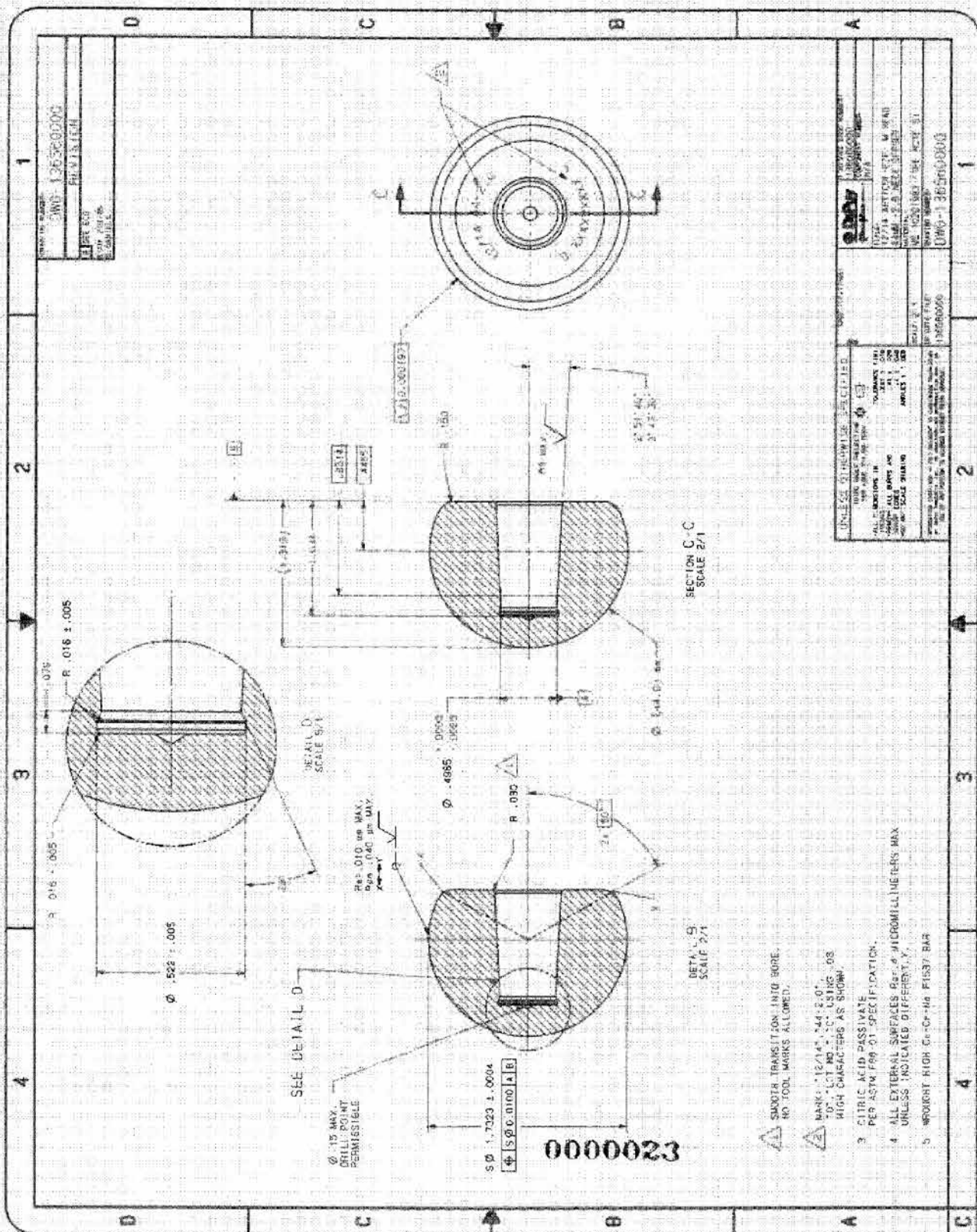
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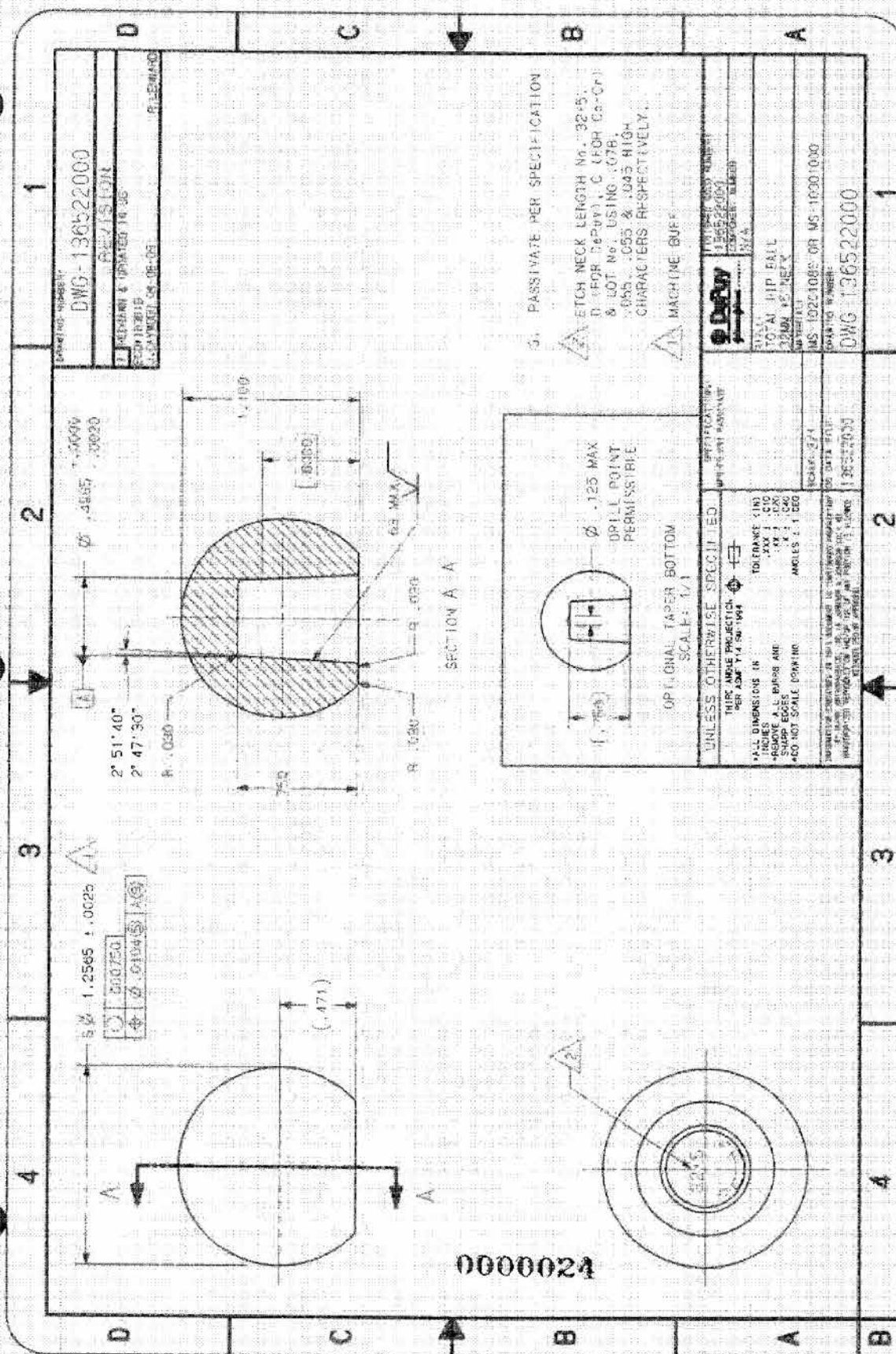
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STATUS: Production

NUMBER: DWG-36522000



DATE PRINTED: 9/28/2006 9:30:30 AM

EXHIBIT 3 COMPATIBLE COMPONENTS

DePuy Femoral Heads

Description	Cleared In:
12/14 taper 40 and 44mm M Spec Co-Cr-Mo Femoral Heads	K060031
11/13 taper 40 and 44mm M Spec Head Co-Cr-Mo Femoral Heads	K060031
36mm S-ROM M Spec Co-Cr-Mo Heads	K851422, K003523
36mm Articul/eze M Spec Co-Cr-Mo Heads	K980513, K003523

DePuy Acetabular Shells

Description	Cleared In:
Pinnacle 100 Series Shells	K001534, K003523
Pinnacle 300 Series Shells	K001534, K003523
Pinnacle Multi-hole Shells	K000306* K001534*
Pinnacle Sector Shells	K001534, K003523
Pinnacle HA Sector	K031495
Pinnacle HA 100	K031495
Pinnacle Standard Profile Shells	K033338
Pinnacle Deep Profile Shells	K033338

*Cleared through internal documentation to this 510(k) in accordance with Blue book Memo #K97-1, documentation on file at DePuy.

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DePuy Compatible Stems

Description	Material	Taper	Cleared In
AML Hip Stem	CoCrMo	12/14	K012364, K003800, K030979, K040627* K061833
Prodigy Hip Stem	CoCrMo	12/14	K914078, K000207 K001778, K040627*
Replica Hip Stem	CoCrMo	12/14	K934334, K003875 K040627*
Vision Solution Std	CoCrMo	12/14	K953703, K953694 K033338, K040627*
Summit Porous Hip Stem	Ti	12/14	K000306, K001991 K011489, K030122, K040627*
Trilock Std Hip Stem	CoCrMo	12/14	K001982, K010367 K869331, K974740 K040627*
Endurance Total Hip Stem	CoCrMo	12/14	K942370 K040627*
Luster Total Hip Stem	CoCrMo	12/14	K983136 K040627*
Summit Cemented Hip Stem	CoCrMo	12/14	K013352, K023453 K040627*
Uni-Rom Hip Stem	Ti	11/13	K974331 K040627*
SROM Hip Stem	Ti	11/13	K851422, K954935, K961939, K040627* K061221
Corail AMT	Ti	12/14	K042992*

* This 510k cleared the stem family for use with metal heads and liners

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WI-0561, Revision B, Attachment B

Research Work Request Add/Change Form

DePuy, a Johnson & Johnson Co.

(574) 267-8143

Requester	Date: 9/28/2006	Lab Use Only	Work Request #: 060177
Requested by:	Rebecca Noftz	Work by:	Peter Liao
Phone Extension:	X5902	Signature:	<i>[Signature]</i> Date: 9/28/2006
Project Number:	MTS27	Notebook #:	

Description of Add/Change:

On the Work Request Form page, Sample Description, Articulate 44mm Heads, 12/14, +5, N=4, the part number should be 1365-62-000 (no rev 1).

On page 3, Table 1, row 2, column 3, the part number should be 1365-62-000 (no rev 1).

Approvals

Research:

Date:

Requester:

Date:

Page 1 of 1

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DePuy, a Johnson & Johnson Co.		Laboratory Work Request Form		(574) 267-8143
Requester	Date: 3/1/2006	Lab Use Only	Work Request #: 060177	
Requested by:	Rebecca Noftz	Work by:	Peter Liao, Charlie Frisinger and Amber Albents	
Phone Extension:	X7404	Signature:	<i>[Signature]</i>	
Project Number:	MTS27	Notebook #:	Date Completed:	7/27/2006

Sample Description:
 Articuleze 28mm Heads, 12/14, +5, N=4 (1365-12-500)
 Articuleze 44mm Heads, 12/14, +5, N=4 (1365-69-000 rev 1)
 Ultamet Metal 28/52mm Inserts, N=4 (1218-89-152)
 Ultamet Metal 44/66mm Inserts, N=4 (1218-87-466)
 Pinnacle Acetabular Shell, N=4 (1217-01-052)
 Pinnacle Acetabular Shell, N=4 (1217-01-066)

Describe: Item #, Material, Processing, Vendor, RMLN, SWOM - Attach certs, if possible

Description of Work Requested:

The purpose of this study was to demonstrate the effect of implant diameters on the wear of a modern metal-on-metal hip implant using a hip simulation machine.

High-carbon CoCrMo (ASTM F1537) wrought femoral head components and acetabular inserts were tested. The test specimens were arranged in two groups (four sets for each) according to their nominal head/insert sizes, including Group A: 28 mm (the small head), and group B: 44 mm (the large head). The actual diameters for the implants were measured using a CMM (Brown & Sharpe, North Kingstown, RI). Surface metrology was performed using a NewView 5000 Interferometer (Zygo Corporation, Middlefield, CT).

The wear test was performed on an 8-station hip joint simulator (MTS, Eden Prairie, MN) using the Paul-type physiological loading (3000 N max. +/- 23° biaxial rocking motion at 1 Hz), with an inverted position (i.e., the head located on top of the insert) for 6 million cycles. The interface was lubricated with bovine serum (HyClone Lab, Logan, UT), which contained 0.2% sodium azide and 20mM EDTA. The protein concentration was 17 mg/ml (approximately 25% of original serum concentration). Wear was assessed by measuring the weight loss every half million cycles. The weight loss was converted to volumetric wear using a density of 8.86 g/cm³. One additional weighing was performed at 0.25 million cycles (MC) to observe the early wear-in of the components. The surface morphology was evaluated using light microscopy.

Results:

The wear results for the small head group consisted of a rapid break-in period (0 to 0.5MC) and a stabilized period with a lower wear rate (1 to 6MC). The break-in period for the large head group was longer than 0.5MC and was chosen at the first million cycles. However, the wear for the large head group was low and appeared to be linear over the six million cycles, suggesting the large head with tight clearance control reached stable wear without the break-in period.

The total volumetric wear over 6 million cycles were $0.56 \pm 0.12 \text{ mm}^3$ and $0.11 \pm 0.02 \text{ mm}^3$ for the small head group and large head group, respectively. The results showed an 80% wear reduction when compared the large head group to the small head group over the six-million test cycles.

The wear rates during the break-in period were $0.85 \pm 0.36 \text{ mm}^3/\text{MC}$ (0 to 0.5MC) and $0.07 \pm 0.02 \text{ mm}^3/\text{MC}$ (0 to 1MC) for the small head and large head group, respectively, suggesting a wear reduction of 92%. The stabilized wear was comparable between two groups (Table).

	Testing Period	28 mm (Small Head Group)	44 mm (Large Head Group)
Wear Rate (mm ³ /million-cycle)	Break-in Wear	0.85 ± 0.36	0.07 ± 0.02
	Stabilized Wear	0.03 ± 0.04	0.02 ± 0.00

The diametrical clearance for each couple remained similar before and after the wear test.

Approvals

Research: *[Signature]* Date: *[Signature]*
 Requester: *[Signature]* Date: *[Signature]*

Rev. 8/2000

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Introduction

The metal-on-metal hip has shown greater wear reduction than the metal-on-polyethylene hip system [1]. Lab simulation showed that most of the metal-on-metal wear occurred during the break-in period [2]. Therefore, it is important to reduce the initial wear of a modern metal-on-metal hip system. Fluid film lubrication formation has been recognized as one of the key factors to wear reduction. Increasing the head size and reducing the diametrical clearance will help establishing fluid film lubrication [3]. Other benefits of large head size include increased range of motion and enhanced stability from hip joint dislocation.

The purpose of this study was to demonstrate the effect of implant diameters on the wear of a modern metal-on-metal hip implant using a hip simulation machine.

Materials and Methods

High-carbon CoCrMo (ASTM F1537) wrought femoral head components and acetabular inserts were tested. The test specimens were arranged in two groups (four sets for each) according to their nominal head/insert sizes, including Group A: 28 mm (the small head), and group B: 44 mm (the large head) (Table 1). The actual diameters for the implants were measured using a CMM (Brown & Sharpe, North Kingstown, RI). Each diameter was calculated by randomly taking 50 points on the spherical surface of the implants. The diametrical clearances were calculated as the difference between the diameters of the inserts and heads. A head-and-insert match was performed to ensure the similar clearance for each group (Table 2). The initial diametrical clearance for the small head group and the large head group were $65.5 \pm 4.4 \mu\text{m}$, and $94.2 \pm 7.3 \mu\text{m}$, respectively. These values were representative of the manufacturing specifications defined for the products. Surface metrology was performed using a NewView 5000 Interferometer (Zygo Corporation, Middlefield, CT) with a scan area of 0.387 mm^2 and a scan length of $20 \mu\text{m}$. Five locations were measured, including the apex and four locations at the 23-degree (each 90-degree apart) from the apex of the specimens. All articulating surfaces were initially polished to an Ra of $0.01 \mu\text{m}$ or less.

The wear test was performed on an 8-station hip joint simulator (MTS, Eden Prairie, MN) using the Paul-type physiological loading (3000 N max, $\pm 23^\circ$ biaxial rocking motion at 1 Hz), with an inverted position (i.e., the head located on top of the insert) for 6 million cycles. The interface was lubricated with bovine serum (HyClone Lab, Logan, UT), which contained 0.2% sodium azide and 20mM EDTA. The protein concentration was 17 mg/ml (approximately 25% of original serum concentration). Wear was assessed by measuring the weight loss every half million cycles. The weight loss was converted to volumetric wear

using a density of 8.86 g/cm³ [2]. One additional weighing was performed at 0.25 million cycles (MC) to observe the early wear-in of the components. The surface morphology was evaluated using light microscopy.

Table 1. Head and Insert Specifications and Part Numbers

Group ID	A (Small Head)	B (Large Head)
Head	Articul/eze (28mm 12/14 +5) (1365-12-500)	Metal Head (44mm 12/14 +5) (1365-69-000 rev 1)
Insert	Metal Insert 28x52 (1218-89-152)	Metal Insert 44x66 (1218-87-466)
Shell	52mm Pinnacle (1217-01-052)	66mm 100 series (1217-01-066)
Insert Thickness	0.2818 in (7.16 mm) Theoretically at dome	0.2719 in (6.90 mm) Theoretically at dome
Specimen #	4 each	4 each
Comments	1. Choose insert thickness similar for two groups 2. Pick high diametrical clearance for worst case scenario	

Table 2. The Test Matrix and Assigned Test Stations

Group ID	Head		Insert		Diametrical Clearance (μm)	Station ID
	Head ID	Lot #	Insert ID	Lot #		
A. Small (28 mm)	M27-H01	1993817	M27-L01	XUA-62	60.45	1
	M27-H02	2048501	M27-L02	XUD-28	65.28	3
	M27-H03	2048501	M27-L03	XNK-75	71.12	5
	M27-H04	2048501	M27-L04	XR8-44	65.02	7
B. Large (44 mm)	M27-BH01	2088190	M27-BL01	4195614	90.17	2
	M27-BH02	2088190	M27-BL02	4195614	94.49	4
	M27-BH03	2088190	M27-BL03	4195614	104.39	6
	M27-BH04	2088190	M27-BL04	4195614	87.88	8

Results and Discussion

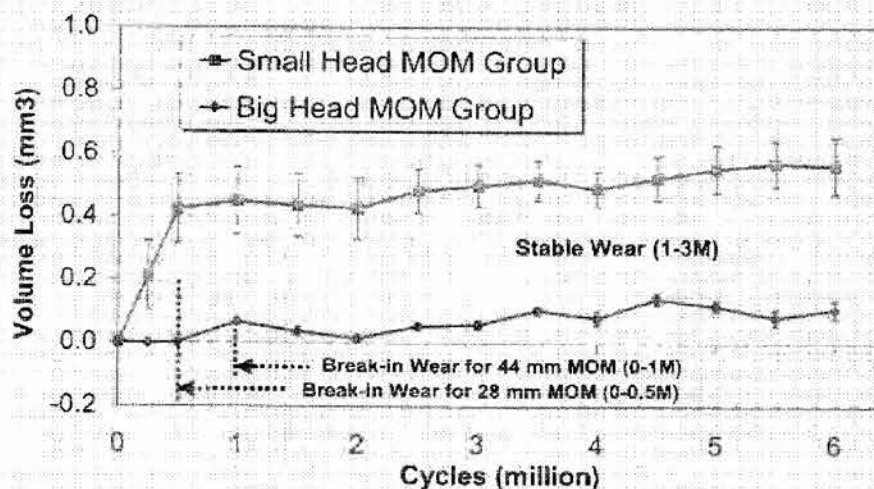
In general, the wear results for the small head group consisted of a rapid break-in period (0-0.5MC) and a stabilized period (1-6MC, Figure 1), which were consistent with the trends in previous studies [3-5]. The break-in period for the large head group was longer than 0.5MC and was chosen at the first million

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cycles based on the total volume loss data (Figure 1). However, the wear for the large head group was low and appeared to be linear over the six million cycles, suggesting the large head with tight clearance control reached stable wear without the break-in period. During 2.5 to 3 million cycles, there was one pair of 28 mm specimens that ran dry due to serum leakage. The test was resumed with replenished serum for the failed station but the data from the failed station was excluded from the analysis.

The total volumetric wear over 6 million cycles were $0.56 \pm 0.12 \text{ mm}^3$ and $0.11 \pm 0.02 \text{ mm}^3$ for the small head group and large head group, respectively (Figure 1). The results showed an 80% wear reduction for the large head group compared to the small head group over the six-million test cycles.

Fig.1 The Accumulated Volume Loss (Combined Wear)



The wear rates during the break-in period were $0.85 \pm 0.36 \text{ mm}^3/\text{MC}$ (0-0.5MC) and $0.07 \pm 0.02 \text{ mm}^3/\text{MC}$ (0-1MC) for the small head and large head group, respectively; suggesting a wear reduction of 92%. The stabilized wear (1-6MC) was comparable between two groups, about $0.03 \pm 0.04 \text{ mm}^3/\text{MC}$ and $0.02 \pm 0.00 \text{ mm}^3/\text{MC}$ for small and large head group, respectively (Figure 2).

For the large head group, the fact that overall wear rate was similar to the stabilized wear rate ($0.02 \text{ mm}^3/\text{MC}$) suggested that the large head metal-on-metal skipped the break-in period and achieved stable wear directly.

The diametrical clearance for each couple remained similar before and after the wear test (Table 3). For the small head group, the clearance changed

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from $65.5 \pm 4.4 \mu\text{m}$ to $62.9 \pm 6.2 \mu\text{m}$. For the large head group, the diametrical clearance changed from $94.2 \pm 7.3 \mu\text{m}$ to $91.8 \pm 8.2 \mu\text{m}$.

Fig.2 The Wear Rate at Different Stage of the Test

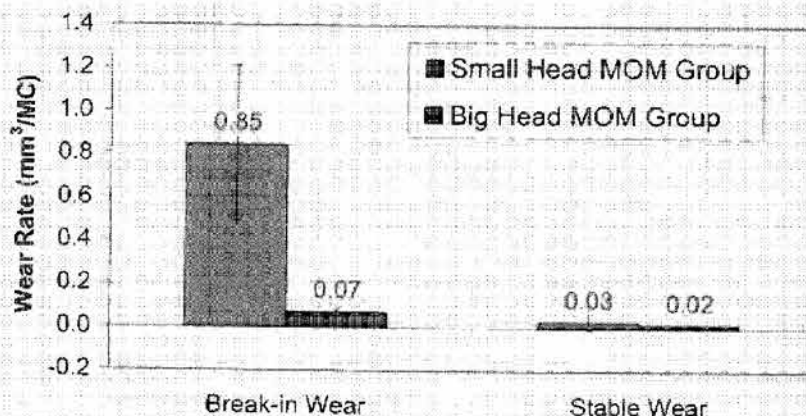


Table 3. Diametrical Clearance Before and After the Wear Test

Group ID	Head ID	Insert ID	Diametrical Clearance (μm)	
			Pre-test	Post-Test
A. Small (28 mm)	M27-H01	M27-L01	60.45	57.66
	M27-H02	M27-L02	65.28	63.50
	M27-H03	M27-L03	71.12	71.37
	M27-H04	M27-L04	65.02	58.93
B. Large (44 mm)	M27-BH01	M27-BL01	90.17	85.85
	M27-BH02	M27-BL02	94.49	90.93
	M27-BH03	M27-BL03	104.39	103.63
	M27-BH04	M27-BL04	87.88	86.61

The surface roughness of the 28 mm heads increased from $0.0076 \pm 0.0008 \mu\text{m}$ to $0.0095 \pm 0.0026 \mu\text{m}$ before and after the test, respectively. For the 44 mm heads, the surface roughness increased from $0.0067 \pm 0.0007 \mu\text{m}$ to $0.0113 \pm 0.0029 \mu\text{m}$ before and after the test, respectively. The surface roughness of the 28 mm inserts increased from $0.0074 \pm 0.0019 \mu\text{m}$ to $0.0118 \pm 0.0106 \mu\text{m}$ before and after the test, respectively. For the 44 mm inserts, the

surface roughness increased from $0.0108 \pm 0.0027 \mu\text{m}$ to $0.0184 \pm 0.0072 \mu\text{m}$ before and after the test, respectively (Table 4).

The average R_{pm} value of the 28 mm heads decreased from $0.0613 \pm 0.0089 \mu\text{m}$ to $0.0376 \pm 0.0111 \mu\text{m}$ before and after the test, respectively. For the 44 mm heads, the average R_{pm} value increased from $0.0406 \pm 0.0046 \mu\text{m}$ to $0.0675 \pm 0.0233 \mu\text{m}$ before and after the test, respectively. The average R_{pm} value of the 28 mm inserts increased from $0.0403 \pm 0.0039 \mu\text{m}$ to $0.0490 \pm 0.0376 \mu\text{m}$ before and after the test, respectively. For the 44 mm inserts, the average R_{pm} value increased from $0.0327 \pm 0.0090 \mu\text{m}$ to $0.0495 \pm 0.0107 \mu\text{m}$ before and after the test, respectively (Table 5).

Table 4. Surface Metrology (R_a) Before and After the Wear Test

Group	Station ID	Head R_a (μm)			Insert R_a (μm)		
		Head ID	Pre-Test	Post-Test	Insert ID	Pre-Test	Post-Test
A. Small (28 mm)	1	M27-H01	0.0087	0.0121	M27-L01	0.0092	0.0031
	3	M27-H02	0.0076	0.0070	M27-L02	0.0086	0.0262
	5	M27-H03	0.0069	0.0114	M27-L03	0.0052	0.0046
	7	M27-H04	0.0071	0.0076	M27-L04	0.0065	0.0131
B. Large (44 mm)	2	M27-BH01	0.0059	0.0074	M27-BL01	0.0098	0.0117
	4	M27-BH02	0.0073	0.0133	M27-BL02	0.0139	0.0184
	6	M27-BH03	0.0062	0.0106	M27-BL03	0.0075	0.0284
	8	M27-BH04	0.0073	0.0138	M27-BL04	0.0118	0.0151

Table 5. Surface Metrology (R_{pm}) Before and After the Wear Test

Group	Station ID	Head R_{pm} (μm)			Insert R_{pm} (μm)		
		Head ID	Pre-Test	Post-Test	Insert ID	Pre-Test	Post-Test
A. Small (28 mm)	1	M27-H01	0.0746	0.0366	M27-L01	0.0398	0.0175
	3	M27-H02	0.0576	0.0269	M27-L02	0.0452	0.1001
	5	M27-H03	0.0575	0.0339	M27-L03	0.0357	0.0243
	7	M27-H04	0.0555	0.0531	M27-L04	0.0404	0.0539
B. Large (44 mm)	2	M27-BH01	0.0356	0.0365	M27-BL01	0.0423	0.0485
	4	M27-BH02	0.0446	0.0876	M27-BL02	0.0326	0.0417
	6	M27-BH03	0.0379	0.0831	M27-BL03	0.0207	0.0649
	8	M27-BH04	0.0444	0.0627	M27-BL04	0.0351	0.0427

The average R_{sk} values became negative at the end of the test. The average R_{sk} value of the 28 mm heads decreased from 0.69 ± 1.04 to -2.97 ± 3.26 before and after the test, respectively. For the 44 mm heads, the average R_{sk}

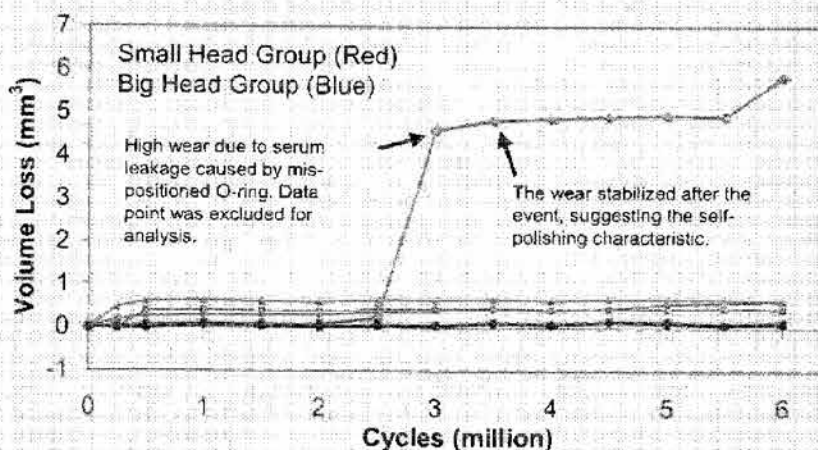
value decreased from 0.05 ± 0.54 to -0.73 ± 0.46 before and after the test, respectively. The average R_{sk} value of the 28 mm inserts decreased from 0.41 ± 0.26 to -2.95 ± 2.30 before and after the test, respectively. For the 44 mm inserts, the average R_{sk} value decreased from -1.24 ± 0.66 to -3.15 ± 0.80 before and after the test, respectively (Table 6).

Table 6. Surface Metrology (R_{sk}) Before and After the Wear Test

Group	Station ID	Head R_{sk}			Insert R_{sk}		
		Head ID	Pre-Test	Post-Test	Insert ID	Pre-Test	Post-Test
A. Small (28 mm)	1	M27-H01	1.9327	-0.6215	M27-L01	0.3217	-0.4521
	3	M27-H02	0.7392	-7.7895	M27-L02	0.7742	-5.0602
	5	M27-H03	0.6185	-1.6154	M27-L03	0.1867	-1.5413
	7	M27-H04	0.7211	-1.8591	M27-L04	0.3363	-4.7513
B. Large (44 mm)	2	M27-BH01	-0.2759	-0.9670	M27-BL01	-0.8110	-4.2276
	4	M27-BH02	-0.4678	-1.2565	M27-BL02	-0.6015	-2.9337
	6	M27-BH03	0.2046	-0.3967	M27-BL03	-1.5286	-2.2929
	8	M27-BH04	0.7491	-0.2940	M27-BL04	-2.0314	-3.1285

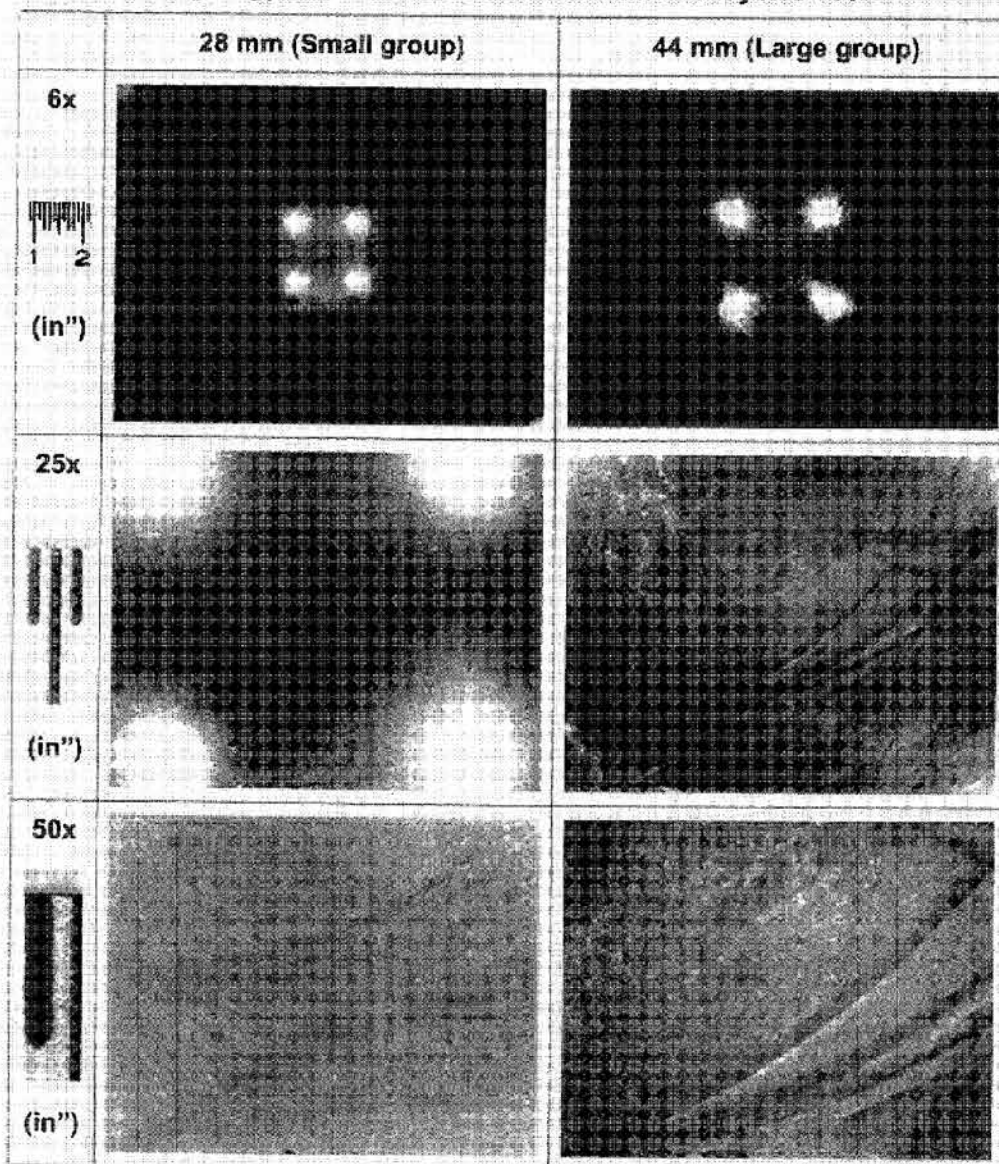
On the station that ran dry, the test specimens experienced high wear and roughened bearing surfaces. A new stabilized state, however, was reached after another half-million test cycles, suggesting a "self-polishing" characteristic of the metal-on-metal bearings (Figure 3).

Fig.3 The Wear Rate at Different Stage of the Test



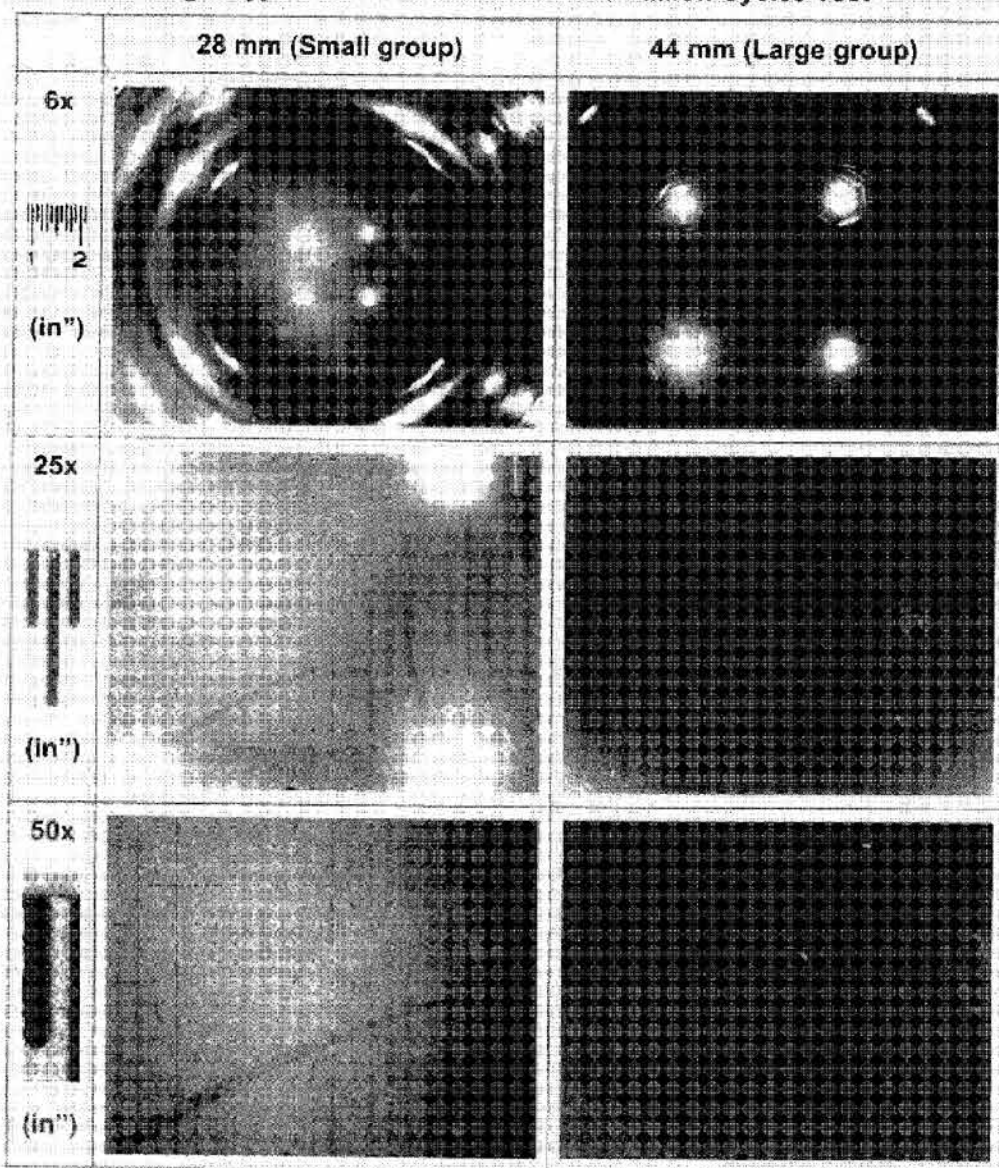
The surfaces of the heads and inserts appeared to be roughened at the articulating area with fine scratches. Typical surface observations for the test specimens are provided in Figure 4 and Figure 5. The whitened articulating area noted in these figures is due to light reflection.

Fig.4 Typical Head Surfaces After 6-million Cycles Test



The curved scratches may be created due to 3rd body particles that were driven by the motion of the test stations. These particles may come from the CoCrMo wear debris of the heads and inserts, which are very hard materials and stayed in the wear interfaces due to the inverted setup of the wear test.

Fig.5 Typical Insert Surfaces After 6-million Cycles Test



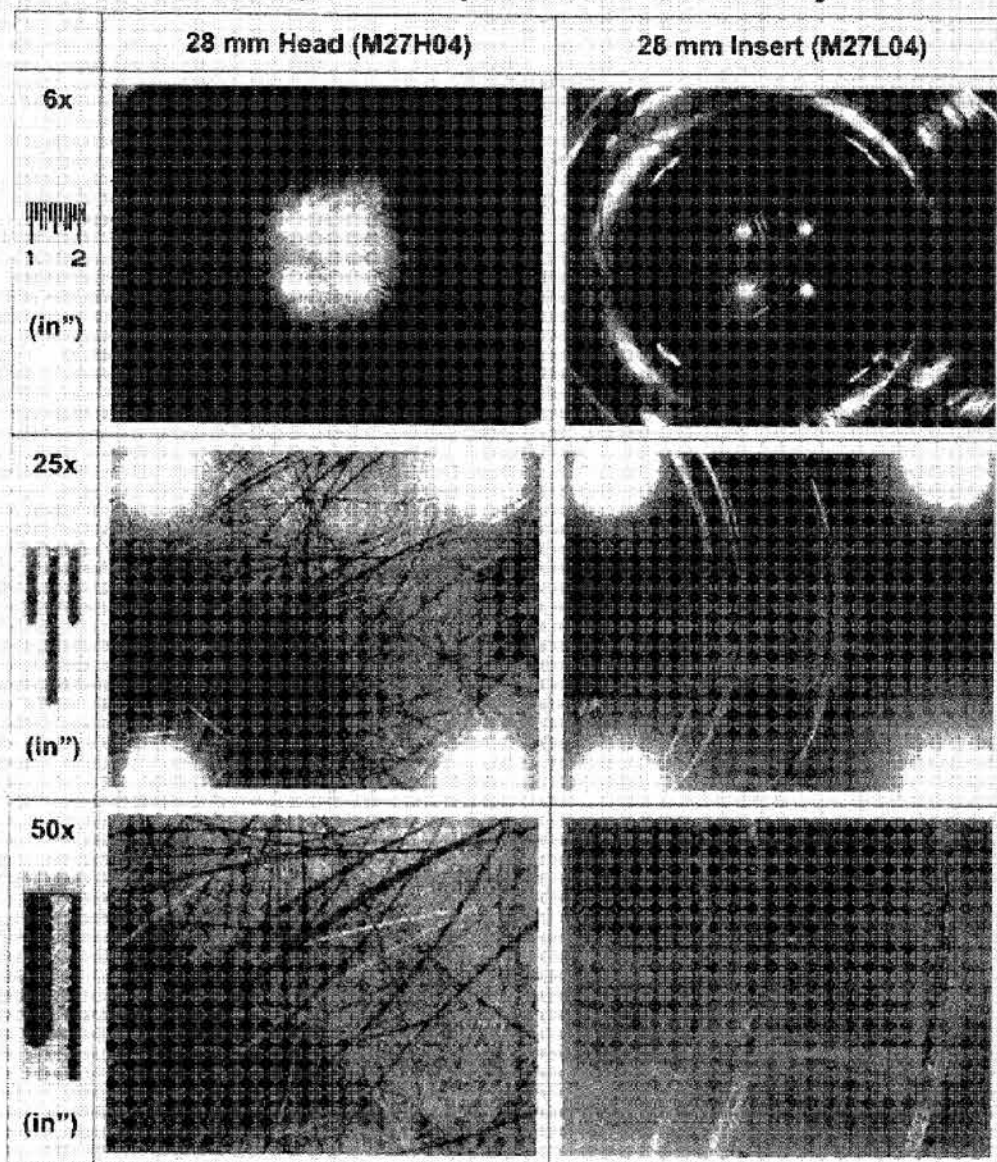
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On the station that ran dry, the test specimens (M27H04 and M27L04) experienced another increased wear from 5.5 to 6-million cycles. The surface had deep and circular scratches, which was due to 3rd body wear. The particle may be trapped at the bearing interface and created gauging lines with the motion of the test station (Figure 6).

Fig.6 The High Wear Couple at the End of 6-million Cycles



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Conclusion

The modern large size metal-on-metal total hip prostheses (44 mm) provided substantial wear reduction compared to the small size (28 mm). The current study demonstrated an 80% overall wear reduction over the six-million cycles test, and, a 92% of wear reduction during the break-in period. This is clinically significant in that reducing the wear rate reduces metal ion release and potentially reduces osteolysis associated with wear of total hip arthroplasty [2].

References

- [1] Dobbs, H. S. (1980). "Survivorship of total hip replacements." J Bone Joint Surg 62B: 168-173.
- [2] Liao, Y.-S. and M. Hanes (2006). The Relationship of Metal-on-Metal Wear and Metal Ion Release in the Serum Lubricant. Orthopaedic Research Society, Chicago, IL.
- [3] Dowson, D., C. Hardaker, et al. (2004). "A hip joint simulator study of the performance of metal-on-metal joints: Part II: design." J Arthroplasty. 19(8 Suppl 3): 124-30.
- [4] Chan, F., J. Bobyn, et al. (1999). "The Otto Aufranc Award - Wear and lubrication of metal-on-metal hip." Clin Orthop Relat Res 369: 10-24.
- [5] Liao, Y.-S., J. C. Fryman, et al. (2004). Effects of Clearance, Head Size and Start-Stop Protocol on Wear of Metal-on-Metal Hip Joint Bearings in a Physiological Anatomical Hip Joint Simulator. Orthopaedic Research Society, San Francisco, CA.

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Deflection Test Summary – Pinnacle liners

PINNACLE XL INSERTS					
36mm ID x 50mm OD		36mm ID x 52mm OD		40mm ID x 56mm OD	
AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)
-36	41	-64	37	-66	33
St Dev 7	St Dev 10	St Dev 14	St Dev 4	St Dev 15	St Dev 16
40mm ID x 58mm OD		44mm ID x 62mm OD		44mm ID x 64mm OD	
AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)
-45	37	-65	53	-46	32
St Dev 6	St Dev 4	St Dev 8	St Dev 12	St Dev 4	St Dev 22

Highlighted data is worst-case insert currently sold.

All the deflection testing was done on a shell-insert combination. The 36x52 insert underwent physical testing (WR050161) prior to the rest of the inserts in order to validate a FEA model: the FEA model was then used to predict what the deflection would be for a variety of sizes. The sizes chosen for commercial launch were based on the FEA results. Additional deflection testing was done on the worst-case new sizes (largest heads in the smallest shells for each head size as well as a representative of each lateralization for final design validation. The results of that test (WR060140) are shown above.

The 36x52 insert inside a multi-hole Pinnacle Shell was determined to be the worst-case combination for two reasons. One: the multi-hole shell would be most susceptible to deflection due to the number of holes. Two: the insert was the largest head size in the smallest shell available on the market, creating a thin insert that was most susceptible to deflection. In addition to product worst case, the load applied to each combination is also considered the worst load that could be experienced in vivo (1810kN per WL Griffin abstract, referenced in FEA report WR050127), and the load was applied over a worst-case area (22.8 mm² - per FEA report). Based on this information, the overall test would be considered the worst scenario possible with products available today. As another consideration, the 36x52 mm insert has been used in the market with the multi-hole shell for 4 years with no reported problems of seizing or binding, so with over 19,000 units sold per year it is considered a successful combination.

The acceptance criteria for the new insert/shell combinations: the new combinations must experience vertical deflection less than or equal to the vertical deflection shown by the current worst-case combination. Vertical deflection was considered to be the most critical as the load was applied vertically, deforming the insert into the clearance space between the head and the insert. Horizontal deflection was considered non-critical as it would deform outward and not encroach on the clearance space.

The results of the analysis for the 36 x 50mm, 40 x 58mm and 44 x 64mm met the acceptance criteria, however the average vertical deflection values for the 40x56 mm and 44x62 mm, were slightly higher than that of the worst-case combination. These results however were considered acceptable because, accounting for standard deviation, 44x62 has the highest deviation at -73 and the lowest at -58. Compared to the range for the current

PROJECT NUMBER: 452-409-013
 ULTAMET METAL-ON-METAL ADDENDUM 0000039
 METAL-ON-METAL XL INSERTS

insert, 36x52, -78 and -50, the 44x62 is well within the acceptance criteria and will be considered a passing design.

Considering standard deviation, 40x56 has the highest deflection at -82 and the lowest at -53. This is only 4 μ m outside of the acceptance criteria range. The standard error was calculated at 9, indicating there is no significant difference between the 40x56 insert and the current size, so the 40x56 is acceptable as is.

There is an additional factor that should be taken into account when examining the results of the deflection test. Dr. Griffin of Charlotte, NC, took measurements in vivo of both the force and the deflection experienced at insertion of a range of cup sizes and patients. He found that the acetabulum exerts a maximum force of 1.81kN during impaction with resulting 0.19 mm of deflection. Dr. Griffin reasoned that the deformed cup would probably be pushed back to round with the insertion of a CoCr metal insert, but he showed concern that the thinner the inserts became the more difficult it would be. In response to this data, DePuy and Dr. Griffin engaged in a cadaveric study to determine if the cup relaxes over time in the acetabulum. Based on the study, it was determined that cups do indeed relax within 10-24 hours after insertion. If this can be shown to happen in a cadaver, then it stands to reason that the same thing will occur in humans because living bone will rebuild itself around the cup.

Attached are the reports of the deflection testing that were conducted.

DePuy, a Johnson & Johnson Co.		Laboratory Work Request Form		(574) 267-8143	
Requester	Date: 08/01/05	Lab Use Only	Work Request #: 050161		
Requested by:	Rebecca Nofz	Work by:	M Biss		
Phone Extension:	5902	Signature:	<i>[Signature]</i>		
Project Number:	452-409-013	Notebook #:	N/A	Date Completed:	8/15/06
Sample Description: N=3 Pinnacle MoM 36IDx52OD Insert P/N-121887352 N=3 Pinnacle Multihole II Acetabular Cup P/N-121720052* *Acetabular cups modified per Appendix B <small>Description: Jean N. Madani, Processing vendor, RMLC SWC, Anach care if possible</small>					

Description of Work Requested:

Measure the deformation of 36.D X 52OD metal on metal cup-liner assemblies with no load applied and a 1.81kN load. Measurements were recorded three times, at angles of 0°, 90°, 180° and 270° from the vertical and 3mm depth from the face of the insert. These quantities were averaged and the difference was taken between the load configurations to determine the overall deformation.

Results:

The following net vertical and horizontal deformations were obtained for each specimen.

36mm X 52mm		
Net Vertical Net Horizontal		
Specimen	(microns)	(microns)
1	-58	41
2	-49	34
3	-76	36
Average	-64	37
St. Dev.	14	2

Appendix A: Figures
 Appendix B: Prints
 Appendix C: DVRT Verification

Approvals	
Researcher: <i>[Signature]</i>	Date: 06-29-06
Requester: <i>[Signature]</i>	Date: 7/1/06
Rev: 8/2005	

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1. Objective:

Determine the amount of deformation under a specified load of 1.81kN.

2. Materials:

The following parts were used for the experiment:

N=3 Pinnacle MoM 36IDx52OD Insert P/N-121887352 (Figure 1)

N=3 52mm Pinnacle Multihole II Acetabular Cup P/N-121720052 (Figure 2)

***Acetabular cup modified per Appendix B print**

3. Methods:

Assemble inserts into corresponding acetabular cups with a 2kN force on the MTS Alliance static load frame with the 2250/bf load cell (DePuy Gage #9007980020000).

Prior to using the *MicroStrain* DVRT sensor, properly verify that the sensor is in working order using the DAQ 3 laptop, National Instruments SCB-68 (shielded connector block), and gage block with the GeneralCalVer6.0 software on DAQ 3 (see Appendix C for report). Once verified, secure the DVRT to the fixture as shown in Figure 3.

Affix the acetabular cup to the fixture by threading the fixture stud into the apex hole, perpendicular to the face of the cup (Figures 2 and 4), while resting one of the two machined flats on the fixture stand (Figure 5).

Secure the fixturing to the MTS Servo-hydraulic test frame, as shown in Figure 6, and align the acetabular cup's face with the load applicator tip (Figure 7).

0kN load

1. With the fixture and acetabular cup assembly fastened to the load frame, insert the DVRT into the fixture. The DVRT tip should be positioned to take measurements 3mm into the cup from the face of the insert. NOTE: Caution should be taken during insertion, as slight angular deflections of the DVRT will cause the DVRT to spike.
2. Begin by taking a measurement in the 0° orientation (Figure 8), followed by moving counterclockwise in 90° increments, while looking into the acetabular cup, and stopping to acquire a measurement at 90°, 180° and 270°. Repeat and record these measurements three times to obtain an average value for each location.

1.81kN load

- a. Once all measurements have been completed without a load, enable the FlexTest SE MTS digital controller in the force control mode and apply a set point of 1.81kN to the cup.
- b. Remove the screw stud from the back of the cup and loosen the two setscrews on the rear of the fixture to slide the vertical fixture plate rearward (Figure 9).
- c. Repeat the DVRT measurement process, steps 1 and 2 above.
- d. At the completion of all measurements, remove the load from the cup, remove the cup from the fixture, reattach the vertical fixture plate and repeat the testing with the next specimen.

Deformation Calculation

By using the deformation from the lower load as a baseline for each sample, the net vertical and horizontal deformations were obtained. These values were calculated by taking the difference of the larger load deformation from the lower load deformation and then adding the corresponding angle's differences together; i.e. 0° and 180° for the vertical and 90° and 270° for the horizontal.

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4. Results:

The following values were obtained for deformation of the cup with a 1.81kN load applied.

36ID X 52OD		
Specimen	Net Vertical (microns)	Net Horizontal (microns)
1	-66	41
2	-49	34
3	-76	36
Average	-64	37
St. Dev.	14	4

5. Discussion/Conclusion:

The net deformation was determined to be 64 microns in the vertical direction and 37 microns in the horizontal direction.

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Appendix A

Figures

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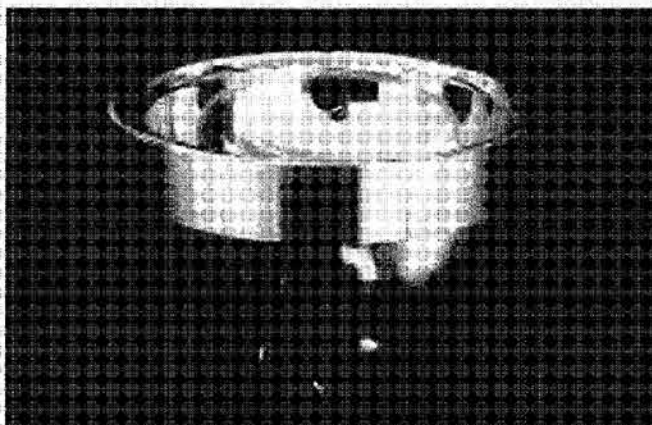


Figure 1: Pinnacle Metal Insert

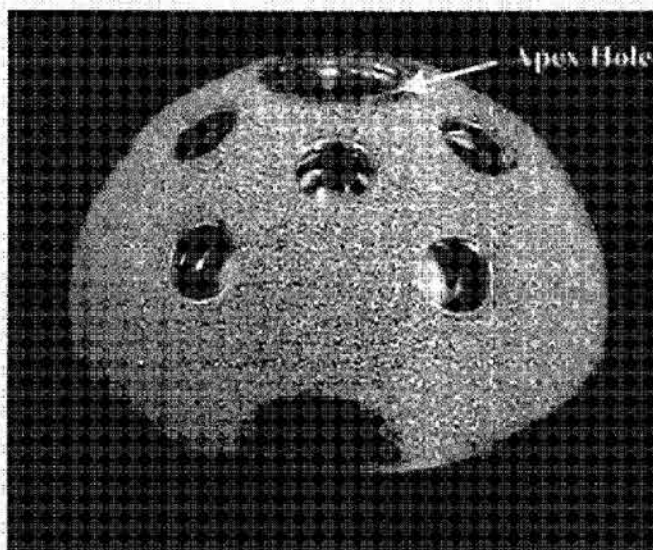


Figure 2: Pinnacle Acetabular Cup

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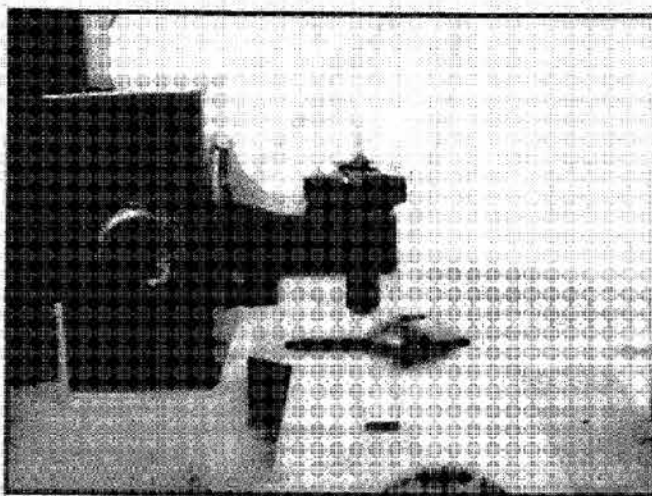


Figure 3: DVRI Secured to Fixture

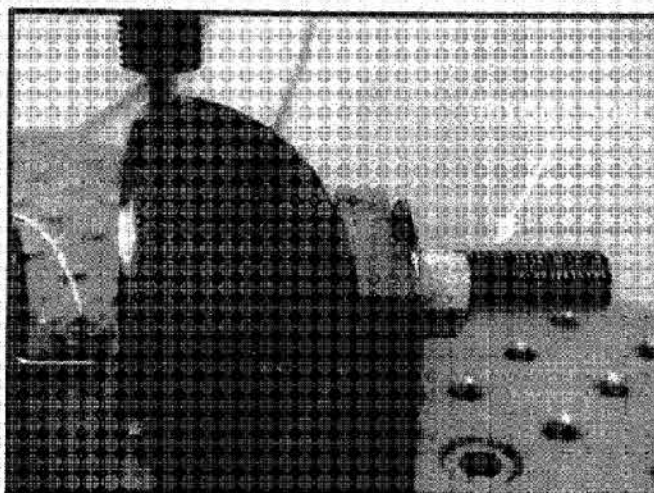


Figure 4: Acetabular Cup Secured to Fixture

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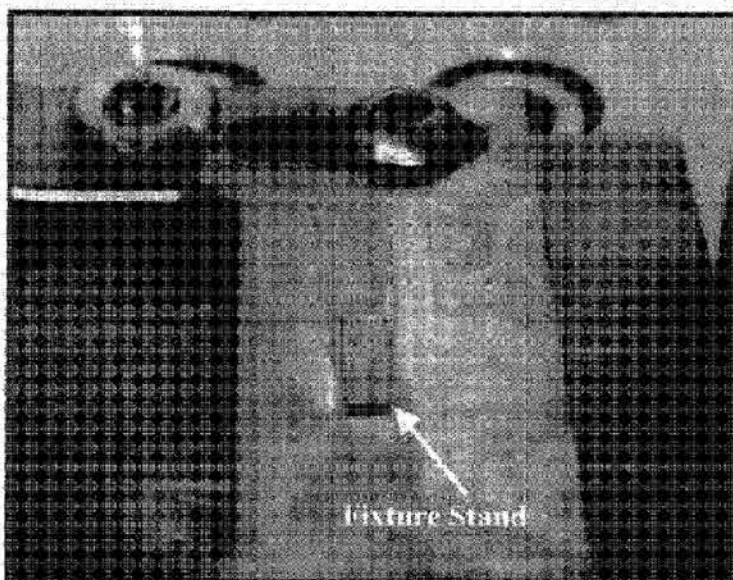


Figure 5: Fixture Stand

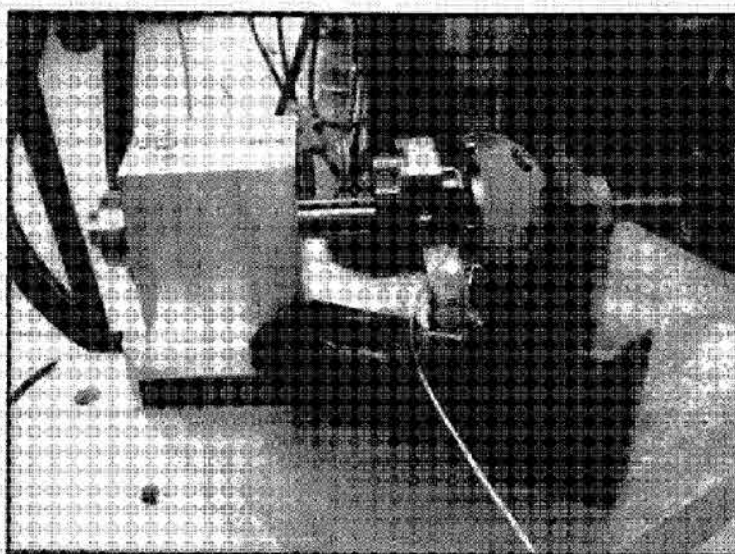


Figure 6: Fixture Secured to MTS Servo Hydraulic Machine

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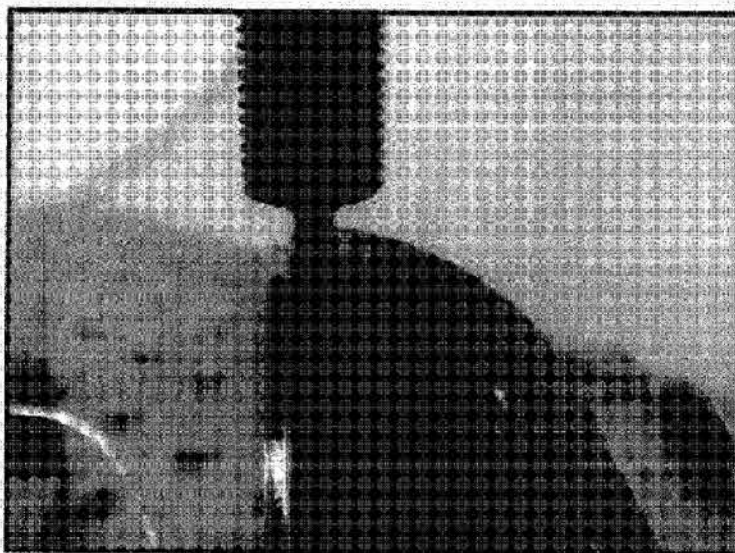


Figure 7: Aligned Load Applicator Tip

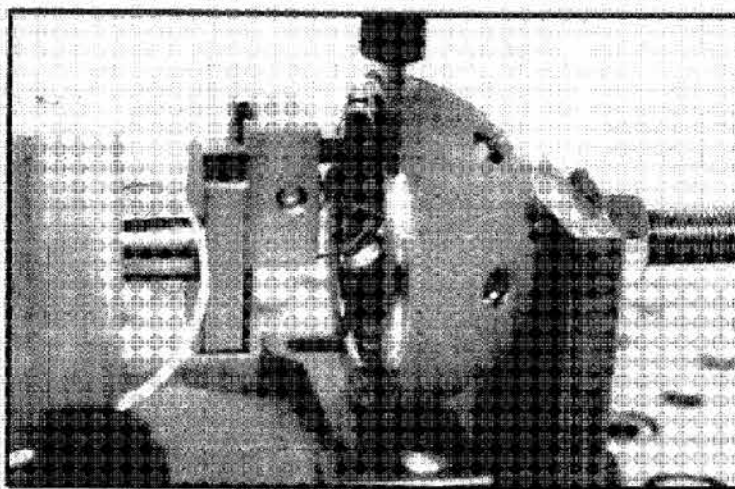


Figure 8: 0° Orientation

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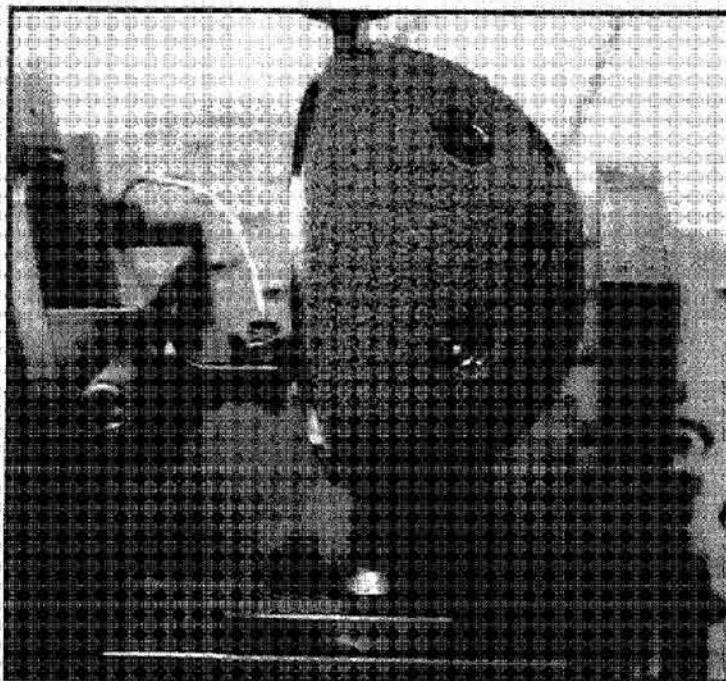


Figure 9: Loaded Specimen Test Set-up

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Appendix B

Prints

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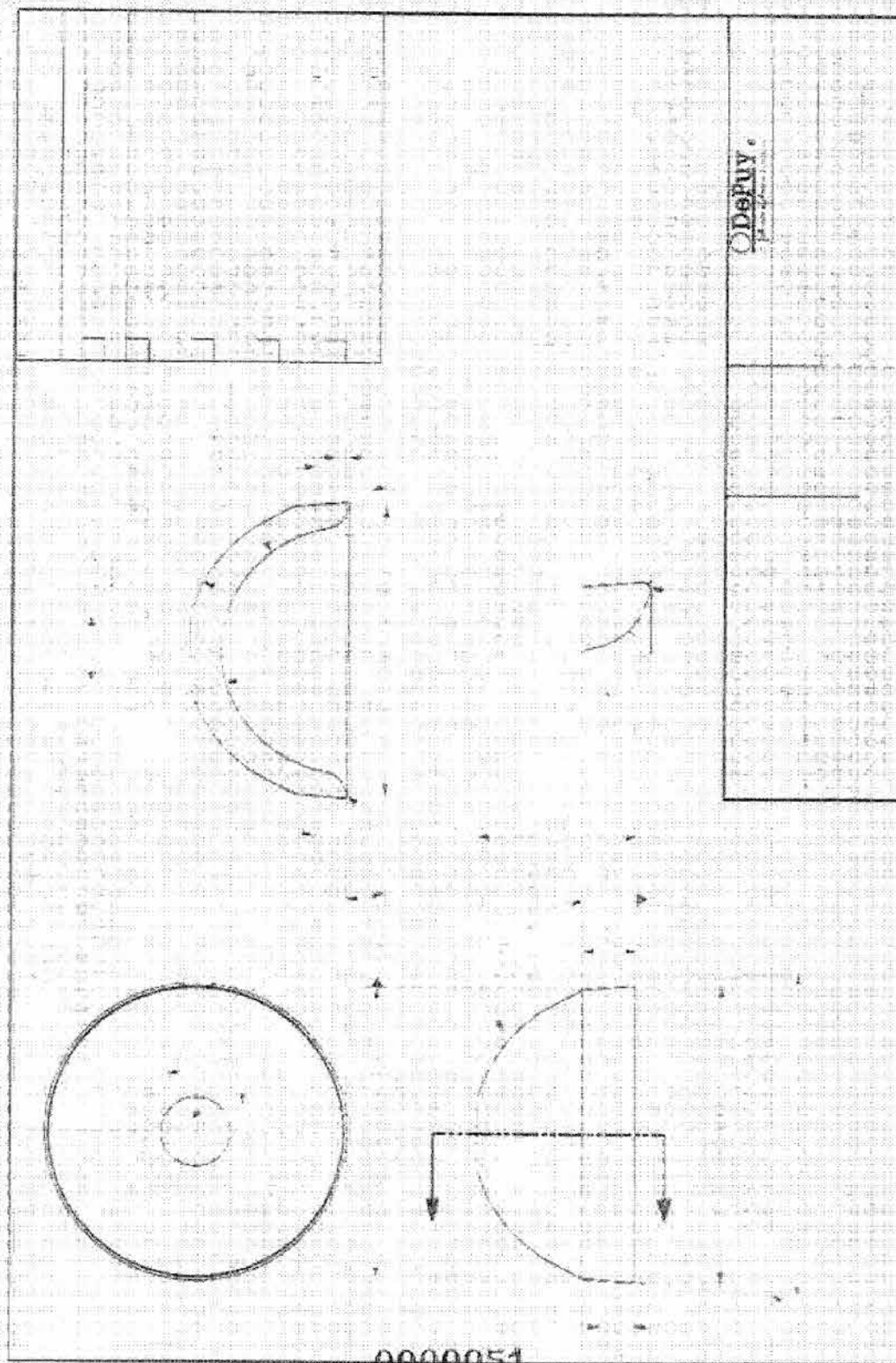
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STATUS: Production

NUMBER: DW 121857352



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REV'D
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STATUS: Medium

NUMBER: DWG-121720052

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Source: <https://www.industrydocuments.ucsf.edu/docs/lpgn0226>

Appendix C

DVRT Verification

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DEPUY022771764

Calibration Test Report for Microstrain Model Hi-Res M-DVRT-75 Gage #: 9038530050000 DVRT

This is the calibration test report for Microstrain Model Hi-Res M-DVRT-75 Gage #. 9038530050000 DVRT

The calibration was performed on 8/1/2005 by Jason Sherman.

The input limits used were 5.000 V and -5.000 V

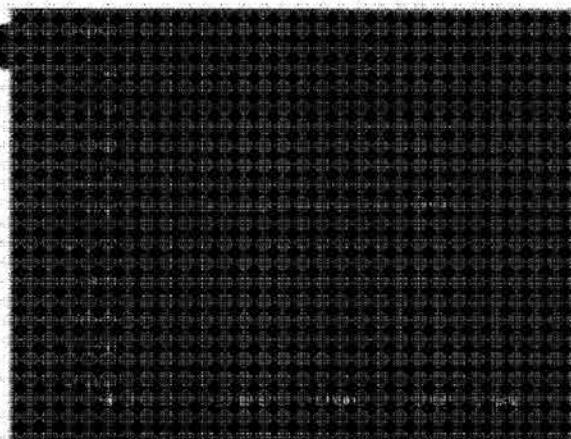
According to the measurements below it **PASSED**.

For a list of the equipment used in testing the unit, please see the equipment list below.

This test was performed per Biomechanics, Testing & Analysis calibration protocols
L:\Warsaw\Orthopaedics\R&DLab\Biomechanics, Testing, Analysis\Sensors\Sensor Calibration Protocols

Calibration Equation Coefficients:

0.009346	1V=1
0.032544	1V=0
R2	0.998213
Full Scale Output (cal units)	0.000000
Non-linearity	inf



y-axis = Measured Units - Measurement Error-Inches

x-axis = Voltage Units - V

	Avg Voltage - V	Stdev Voltage - V	Measured Value- Inches	Measurement Error- Inches
Point 1	-3.283447	0.000733	0.000000	0.000024
2	-2.546321	0.000396	0.010038	0.000062
3	1.491716	0.000204	0.020076	0.000100
4	-0.273923	0.000975	0.030114	0.000138
5	0.936411	0.001214	0.040153	0.000176
6	1.958401	0.000898	0.050191	0.000214

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7 2 343776 0 000266 0 056210 0 000233

The test was run with the following test equipment:

1. DAQ 4
2. DAQ 1 (SCB-68)
3. DAQ 1 PCMCIA Card
4. 9038560050000
5. 82077050000

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DEPUY022771766

DRAFT**DePuy Pinnacle Acetabular Metal Inserts**

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Description

The DePuy Pinnacle Acetabular Cup System is comprised of a metal acetabular shell designed to accept alternative bearing inserts. The Pinnacle metal insert mechanically locks with the metal shell via a taper junction.

Do not mix inserts and shells from different systems. Pinnacle Acetabular Cup Inserts can be used only with Pinnacle Acetabular Shells.

Indications

Pinnacle Acetabular Cups are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Information for Use

An instrumentation system, as well as a system of trial components, is available to assure proper fit and alignment of the prosthesis. Correct fit and alignment will reduce stresses at interface surfaces to enhance implant fixation. The surgeon should refer to the appropriate surgical technique manual on use of the instrument system and implantation of the prosthesis. A special instrument is provided to enable the surgeon to remove the insert once it has been fitted in place.

Contraindications

Use is contraindicated in cases with active or recent joint sepsis, insufficient bone stock, marked atrophy or deformity in the upper femur, skeletal immaturity, or where loss of musculature or neuromuscular disease would render the procedure unjustifiable.

Warnings

For metal-on-metal articulation, Pinnacle Acetabular Inserts are intended for use only with DePuy 28mm, 36mm, 40mm and 44mm diameter M-Spec Co-Cr-Mo femoral heads labelled for metal-on-metal use. Inserts with a 28mm inner diameter should be used with 28mm femoral heads only. Inserts with a 36mm inner diameter should be used with 36mm femoral heads only. Inserts with a 40mm inner diameter should be used with the 40mm femoral heads only. Inserts with a 44mm inner diameter should be used with the 44mm femoral heads only.

Improper prosthesis selection or alignment, inadequate fixation, use where contraindicated or in patients whose medical, physical, mental or occupational conditions will likely result in extreme stresses to the implant may result in premature failure due to loosening, fracture or wear. Postoperative care is extremely important. The patient should

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be instructed on the limitations of the device and should be cautioned regarding load bearing, ranges of motion and activity levels permissible. Early motion and load bearing should be carefully monitored.

This implant should not be used with other manufacturers' components. Use of components other than those recommended could lead to loosening, wear, fracture during assembly and premature failure. Use the Pinnacle metal insert only with the Pinnacle Acetabular Shell.

The inner diameter of the insert must correspond to the hip head size. Use of an insert with a non-matching hip head size (e.g. 28mm inner diameter insert with a 22mm head) will result in accelerated wear and early failure.

Metal-on-metal articulation must utilise DePuy heads especially designed for this purpose

Precautions

To prevent contamination of this prosthesis, keep free of lint and powders. Do not open the package until surgery. Do not place the implant in contact with prepared bone surface before the final decision to implant has been made.

An implant should never be re-used. Any implant, once used, should be discarded. Even though it appears undamaged, it may have small defects and internal stress patterns that may lead to failure.

Likewise, a new implant should be handled carefully to avoid damage that could compromise the mechanical integrity of the device and cause early failure or loosening.

The wear rate of prosthesis contact surfaces is greatly accelerated if loose fragments of bone cement become detached and act as an abrasive in the bearing surfaces. When using bone cement, care should be taken to remove all excess cement from the periphery of the implant.

The highly polished bore of the insert should not come into contact with abrasive surfaces, as this may damage the bore and affect performance. In addition, all mating surfaces should be clean before assembly to ensure proper seating. If the insert is not properly seated into the shell it may become loose.

Adverse Effects

Peripheral neuropathy, deep wound infection, and heterotopic bone formation have been reported following hip replacements.

Subclinical nerve damage has also been reported more frequently, often associated with surgical trauma. Dislocation and subluxation resulting from improper positioning and/or muscle and fibrous tissue laxity may also occur, as may loosening and subsequent failure of the total hip prosthesis.

Histological reactions have been reported as an apparent response to exposure to a foreign material. The actual clinical significance of these reactions is unknown.

Implanted metal alloys release metallic ions into the body. In situations where bone cement is not used, higher ion release due to increased surface area of a porous coated prosthesis is possible.

There have been reports of failure of bone to grow into porous surfaces and fix components. Shedding or fragmentation of the porous surface has been reported, with potential for release of metallic debris into the joint space. Radiolucencies of bone adjacent to porous surfaces have been noted, although the clinical significance of this observation is uncertain in many cases.

Serious adverse effects may necessitate surgical intervention.

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Sterility and Handling

Pinnacle acetabular metal inserts are supplied sterile by exposure to gamma irradiation.

DO NOT RESTERILIZE and DO NOT USE if the package is damaged or broken and sterility may be compromised.

Components may not be resterilized by the hospital because of the possibility of damaging the articulating and interfacing surfaces of the implant and/or damaging or contaminating the porous surface.

The care and handling of porous coated implants demands greater attention because of the increased potential for particulate and microbiological contamination. Body fluids, tissues and particulate matter adhere to the beaded surface. Therefore, it is critical to minimize handling of the prosthesis.

The package should be opened only after the correct size has been determined, as opened packages may not be returned for credit.

Further information is available from your DePuy representative on request.

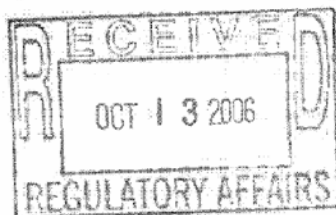
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IFU-78004780
Rev. D

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

October 06, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

Memorandum



To: K062426

From: Anne Schuler

Date: October 18, 2006

Re: Request for additional information

Julie Gantenberg called on October 18, 2006 to request an updated "Indications for Use" page for K062426. The page in the original submission did not have "Prescription Use" checked off. An updated page was e-mailed to Julie on 10-18-06.

Indications for Use

510(k) Number (if known): K062426

Device Name: DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners

Indications for Use:

The Pinnacle Metal-On-Metal Acetabular Cup Liners are indicated for use as the acetabular component in total hip replacement procedures for patients suffering severe pain and disability due to structural damage in the hip joint from rheumatoid arthritis, osteoarthritis, post-traumatic arthritis, collagen disorders, avascular necrosis, and non-union of femoral fractures. Use of the prosthesis is also indicated for patients with congenital hip dysplasia, *protrusio acetabuli*, slipped capital femoral epiphysis and disability due to previous fusion, where bone stock is inadequate for other reconstruction techniques.

The Pinnacle Metal-On-Metal Acetabular Cup Liners are intended for use with DePuy Pinnacle Acetabular Shells and M-Spec Co-Cr-Mo femoral heads only.

Prescription Use XX
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dear Ms. Schuler,

Thank you for permission of this email (provided in your cover letter). To complete our review of your Special 510(k), DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners, K062426/S1, we will need to place your document on hold until we receive the information presented below. Please send in your response in duplicate to the Document Mail Center via standard mail.

If the information, or a request for an extension of time, is not received within 30 days, we will consider your premarket notification to be withdrawn and your submission will be deleted from our system. If you submit the requested information after 30 days it will be considered and processed as a new 510(k)(21 CFR 807.87(l)); therefore, all information previously submitted must be resubmitted so that your new 510(k) is complete. Please note our guidance document entitled, "Guidance for Industry and FDA Staff FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the additional information request.

Please be advised that the FDA Guidance identified above also states "FDA generally will utilize a maximum of three cycles of FDA review to reach a SE or NSE decision. The first review cycle begins upon receipt of the original 510(k) submission, and subsequent review cycles start when we receive responses to our requests for AI by letter. Thus, if there are multiple review cycles, FDA intends to issue a final decision following its review of industry's response to a second AI request. In general, if unresolved deficiencies exist following FDA's review of a response to a second AI request, FDA will issue an NSE letter."

If you need to contact me, please email me at julie.gantenberg@fda.hhs.gov.

PLEASE EMAIL ME TO VERIFY RECEIPT OF THIS REQUEST.

In your S1 response dated October 5, 2006, in item 2b(2), you provided a rationale for not providing additional flexion/extension frictional torque verification activities on the subject 44 M-Spec head/liner couple. This rationale is not adequate. While the chemistries of the subject wrought CoCrMo (ASTM F1537) are similar to those of the cast CoCrMo (ASTM F75) predicate, we believe that you need to demonstrate the flexion/extension frictional torque is adequate for the subject wrought 44 M-Spec head/liner couple. Therefore, please provide a revised Design Control Activities Summary whereby you have clearly defined the quantitative acceptance criteria in all acceptance criteria columns and performed additional flexion/extension frictional torque verification activities on the subject wrought 44 M-Spec head/liner couple. Please include a rationale for the worst case test conditions chosen (diametrical clearances, etc.). We suggest a sample size of three for these particular verification activities.

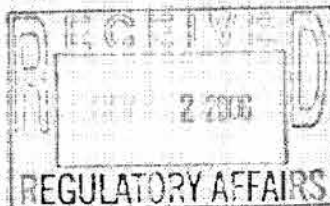
Please email me if you have any questions. We look forward to receiving your response soon.

Sincerely,
Julie B. Gantenberg, M.S.
Biomedical Engineer
FDA Reviewer for DGRND/OJDB

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

October 26, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Product: DEPUY PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>.

If after 30 days the additional information (AI), or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system (21 CFR 807.87(l)). Please note our guidance document entitled, "Guidance for Industry and FDA Staff, FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request. The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. You may review this document at <http://www.fda.gov/cdrh/mdufma/guidance/1219.html>. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission. Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health



DePuy Orthopaedics, Inc.
PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA
Tel: +1 (574) 267-8143

November 21, 2006

Julie Gantenberg
Food and Drug Administration
Center for Devices and Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850


**Re: Request for 30-Day Extension, K062426/S1 DePuy Pinnacle Metal-on-Metal
Acetabular Cup Liners**

Dear Ms. Gantenberg:

DePuy would like to request a 30-day extension to respond to the deficiencies in your correspondence dated October 26, 2006 regarding K062426 DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners. The information requested requires additional time to complete.

Please contact me directly at 574-372-7098, or at aschuler@dpus.jnj.com if you have any questions or need any additional information regarding this request.

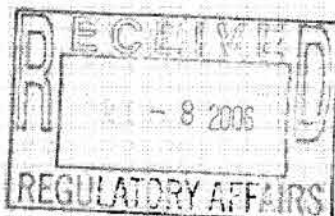
Sincerely,


Anne M. Schuler
Sr. Regulatory Affairs Associate

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

November 30, 2006



Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
700 ORTHOPAEDIC DR.
P.O. BOX 988
WARSAW, IN 46581
ATTN: ANNE M. SCHULER

510(k) Number: K062426
Device: DEPUY PINNACLE
METAL-ON-METAL
ACETABULAR CUP
LINERS

Extended Until: 26-DEC-2006

Based on your recent request, an extension of time has been granted for you to submit the additional information we requested.

If the additional information (AI) is not received by the "Extended Until" date shown above, your premarket notification will be considered withdrawn (21 CFR 807.87(1)). If the submitter does submit a written request for an extension, FDA will permit the 510(k) to remain on hold for up to a maximum of 180 days from the date of the AI request.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (240) 276-4040.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k): Premarket Notification

December 1, 2006

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Attn: Ms. Gantenberg

Re: 2nd Request for Additional Information - K062426 DePuy Pinnacle Metal-on-Metal
Acetabular Cup Liners

Dear Ms. Gantenberg


DePuy Orthopaedics, Inc. submits the enclosed documentation in duplicate as an addendum to the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners K062426, currently under review by FDA. This submission is made to comply with the request for additional information made by e-mail on October 26, 2006.

Pursuant to 21 CFR 807.95(c) (3), DePuy considers our intent to market this device and this 510(k) submission to be confidential commercial information and requests that FDA treat it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

DePuy Orthopaedics acknowledges that the introduction of this device into domestic commercial distribution will be contingent upon written clearance of the 510(k) by the Food and Drug Administration

Thank you in advance for your consideration of our application. If there are any further questions regarding this submission, please feel free to contact Kathy Harris at (574) 372-7082 or email at kharris@dpyus.jnj.com.

Regards,


Anne M. Schuler
Sr Regulatory Affairs Associate
DePuy Orthopaedics, Inc.

**Addendum II to DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners 510(K),
K062426**

Request for Additional Information, October 26, 2006

Question:

In your S1 response dated October 5, 2006, in item 2b(2), you provided a rationale for not providing additional flexion/extension frictional torque verification activities on the subject 44 M-Spec head/liner couple. This rationale is not adequate. While the chemistries of the subject wrought CoCrMo (ASTM F1537) are similar to those of the cast CoCrMo (ASTM F75) predicate, we believe that you need to demonstrate the flexion/extension frictional torque is adequate for the subject wrought 44 M-Spec head/liner couple. Therefore, please provide a revised Design Control Activities Summary whereby you have clearly defined the quantitative acceptance criteria in all acceptance criteria columns and performed additional flexion/extension frictional torque verification activities on the subject wrought 44 M-Spec head/liner couple. Please include a rationale for the worst case test conditions chosen (diametrical clearances, etc.). We suggest a sample size of three for these particular verification activities.

Response:

The Design Control Activities Summary Table has been revised to further define the acceptance criteria for each verification activity and to include flexion/extension frictional torque verification activities for the subject wrought 44mm head/liner couple.

The flexion/extension frictional torque analysis was conducted using a sample size of four 44 x 66mm liners coupled with 44mm M-Spec heads as the test group and four 55 x 62mm ASR bearing couples as the control group. The 44 x 66mm head/liner couple was considered to represent the worse case conditions for the subject liners because this combination provides the largest head diameter in the current Pinnacle MoM system and past testing experience has shown that larger heads generate the highest frictional torque. In addition to head diameters previous testing has also shown that larger clearances generate higher frictional torque than lower clearances. In this case, both the subject Pinnacle and predicate ASR heads and liners/cups are held to a tightly controlled clearance (80um - 120um) so there is very little difference between a low clearance and high clearance within print specifications. For the frictional torque analysis conducted the Subject Pinnacle heads and liners were sorted to provide the highest clearances possible for the test which were 105, 106, 107 and 113 um with a mean 107.75 um. Although these conditions were not the extreme worst case allowed (120um), the difference between the mean and the maximum clearance (12.25um) was considered insignificant and, as shown in previous internal testing, would not affect frictional torque. The previously conducted internal test demonstrated a larger clearance must be significantly larger to product a statistically higher frictional torque. ASR heads and cups were chosen at random from the shelf, presenting with a mean clearance of 94um.

The revised Design Summary table is provided as an attachment to this addendum.

Revised Table 2. Device Modifications, Risks, & Design Control Activities

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
1. Increased Inner Diameter of liner to 40 and 44 mm	1. Effect on wear properties	In-vitro Hip Simulator Wear study - non-clinical study to evaluate the wear performance of the liners. The study was conducted on a hip-joint simulator for 6 million cycles using four subject 44mm liners with 44mm M-Spec heads (test group) and four predicate 28mm liners with 28mm heads (control group). The head/liner interface was lubricated with bovine serum. Wear was determined by measuring the weight loss every half million cycles.	The subject liners must have an average wear rate less than or equal to that of the predicate 28mm MOM liner during both the break-in period and during steady-state wear. The total average wear volume must be less than or equal to that of the 28mm MOM liner after 6 million cycles.	The total average wear over 6 million cycles was $0.56 \pm 0.12 \text{ mm}^3$ for the 28mm liners and $0.11 \pm 0.02 \text{ mm}^3$ for the 44mm liner. The wear rates during the break-in period were $0.85 \pm 0.48 \text{ mm}^3$ for the 28mm liners and $0.07 \pm 0.02 \text{ mm}^3$ for the 44 mm liner. The results demonstrate a 92% wear reduction during the break-in period and a 80% wear reduction overall with the subject 44 mm liner as compared to the predicate 28mm liner. The requirements of the test were met. A complete test report is provided in Exhibit V.
		Diametrical Clearance of the MOM interface is critical to wear performance, therefore diametrical clearances of head/liner interface were determined for the subject liners and compared to the predicate devices.	Diametrical clearances of subject liners must be equal to or greater than that of the predicate 36mm Pinnacle MOM liners.	Diametrical clearances of the predicate 36mm Pinnacle MOM liner, the comparable ASR MOM bearing groups and the 40 and 44 mm Pinnacle MOM subject liners are presented in Table 1 of Section 2 of this submission. The Diametrical clearances of the subject liners are equal to those of the predicate devices. The test requirements were met.

2. Cup loosening due to increased friction moment from large MOM interface	<p>Flexion/Extension Frictional Torque Test – Analysis to measure the frictional torque generated during motion of the worse case 44mm subject liner/head bearing couple. Four sets of 44x66mm subject liners coupled with 44 mm M-spec heads were used for the test group and 4 sets of predicate 55x62mm ASR cup/head combinations were used for the control group. The bearing pairs were tested in a Prosim Friction Simulator test machine. The implants were tested in an inverted position with a flexion/extension motion of +/- 25 ° applied to the head. The test was run at 1Hz with a peak load of 2 kN and a swing load of 300N. Water was used as the lubricant as it is considered to generate the highest frictional torque in a metal-on-metal bearing. Data was analyzed after 90 cycles and mean frictional torque values calculated for the test and control groups.</p>	<p>Frictional torque values for the 44x66 mm subject liner must be less than or equal to the values for the predicate 55x62mm ASR system.</p>	<p>The table below lists the mean frictional torque and peak frictional torque values calculated for the subject 44x66 Pinnacle and predicate 55x62 ASR devices following 90 cycles on the Prosim Friction Simulator:</p> <table><tr><th colspan="3">Frictional torque values</th></tr><tr><th>GROUP</th><th>MEAN FRIC-TIONAL TORQUE (Nm)</th><th>PEAK FRIC-TIONAL TORQUE (Nm)</th></tr><tr><td>44 x 66mm (subject)</td><td>8.2</td><td>10.1</td></tr><tr><td>55 x 62mm (predicate)</td><td>10.0</td><td>11.9</td></tr></table> <p>Based on the results the requirements of the test were met.</p>	Frictional torque values			GROUP	MEAN FRIC-TIONAL TORQUE (Nm)	PEAK FRIC-TIONAL TORQUE (Nm)	44 x 66mm (subject)	8.2	10.1	55 x 62mm (predicate)	10.0	11.9
Frictional torque values															
GROUP	MEAN FRIC-TIONAL TORQUE (Nm)	PEAK FRIC-TIONAL TORQUE (Nm)													
44 x 66mm (subject)	8.2	10.1													
55 x 62mm (predicate)	10.0	11.9													
3. Range of Motion (ROM)	<p>Range of Motion Analysis – ROM for the smallest 40 and 44 mm subject liners was determined Anterior/Posterior (A/P) and Medial/Lateral (M/L). Values were compared to ROM values for the 36mm predicate liners.</p>	<p>ROM of subject liners must be greater than or equal to the predicate 36mm Pinnacle MOM liners.</p>	<p>ROM values for the 40 and 44 mm subject liners were greater than those of the 36mm predicate liner, the requirements of the test were met. Results are summarized in the table below.</p> <table><tr><th>LINER(mm)</th><th>A/P ROM</th><th>M/L ROM</th></tr><tr><td>36 x 52</td><td>151°</td><td>142.5°</td></tr><tr><td>40 x 56</td><td>155.7°</td><td>148.1°</td></tr><tr><td>44 x 62</td><td>159.9°</td><td>149.4°</td></tr></table>	LINER(mm)	A/P ROM	M/L ROM	36 x 52	151°	142.5°	40 x 56	155.7°	148.1°	44 x 62	159.9°	149.4°
LINER(mm)	A/P ROM	M/L ROM													
36 x 52	151°	142.5°													
40 x 56	155.7°	148.1°													
44 x 62	159.9°	149.4°													

2.Decreased Outer Diameter of 36mm liner to 50mm	Liner Deformation	Deformation test – Analysis to determine the amount of deformation to the liner under load. The deformation of 3 of the 36mm x 50mm subject liners and 3 of the predicate 36mm x 52mm liners was determined under a 1.81kN load.	The 36 x 50mm subject liner must experience vertical deflection less than or equal to the vertical deflection shown by the 36 x 52mm predicate liner. Vertical deflection was considered to be the most critical as the load was applied vertically, deforming the insert into the clearance space between the head and the insert. Horizontal deflection was considered non-critical as it would deform outward and not encroach on the clearance space.	The 36mm x 50mm subject liner had an average vertical deflection less than that of the predicate device, the liners met the requirements of the test. The results are summarized in the table below.																
<div>PINNACLE METAL INSERTS</div> <table><tr><th colspan="2">36mm ID x 50mm OD (subject liner)</th><th colspan="2">36mm ID x 52mm OD (predicate)</th></tr><tr><td>AVG Net Vertical (um)</td><td>AVG Net Horizontal (um)</td><td>AVG Net Vertical (um)</td><td>AVG Net Horizontal (um)</td></tr><tr><td>-36</td><td>41</td><td>-64</td><td>37</td></tr><tr><td>St Dev 7</td><td>St Dev 10</td><td>St Dev 14</td><td>St Dev 4</td></tr></table>					36mm ID x 50mm OD (subject liner)		36mm ID x 52mm OD (predicate)		AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)	-36	41	-64	37	St Dev 7	St Dev 10	St Dev 14	St Dev 4
36mm ID x 50mm OD (subject liner)		36mm ID x 52mm OD (predicate)																		
AVG Net Vertical (um)	AVG Net Horizontal (um)	AVG Net Vertical (um)	AVG Net Horizontal (um)																	
-36	41	-64	37																	
St Dev 7	St Dev 10	St Dev 14	St Dev 4																	
Complete test report is on file at DePuy.																				

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

December 04, 2006



Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

DEPUY ORTHOPAEDICS, INC.
 700 ORTHOPAEDIC DR.
 P.O BOX 988
 WARSAW, IN 46581
 ATTN: ANNE M. SCHULER

510(k) Number: K062426
 Product: DEPUY PINNACLE
 METAL-ON-METAL
 ACETABULAR CUP
 LINERS

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review. Please refer to this guidance for information on current fax and e-mail practices at www.fda.gov/cdrh/ode/a02-01.html. On August 12, 2005 CDRH issued the Guidance for Industry and FDA Staff: Format for Traditional and Abbreviated 510(k)s. This guidance can be found at <http://www.fda.gov/cdrh/ode/guidance/1567.html>. Please refer to this guidance for assistance on how to format an original submission for a Traditional or Abbreviated 510(k).

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so in 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the
Division of Small Manufacturers International and Consumer Assistance
(DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041,
or contact me at (240) 276-4040.

Sincerely yours,

Marjorie Shulman

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

From: Gantenberg, Julie *
Sent: Friday, December 08, 2006 9:41 AM
To: 'kharris@dpyus.jnj.com'
Cc: Gantenberg, Julie *; Foy, Jonette
Subject: K062426 additional information needed by 12/13
Importance: High

Dear Ms. Harris,

Anne Schuler informed me that you are the new contact person on the K062426 510(k) submission. We have reviewed your supplement submission dated December 1, 2006 for the K062426/S2 DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners. In order to complete this review, we request a response to the question posed below. Please either email your response to julie.gantenberg@fda.hhs.gov or fax to (240) 276-3602.

ATTN to: Julie B. Gantenberg, FDA Reviewer for DGRND/OJDB
 c/o Michael Courtney

Please respond to this request by **close of business eastern standard time on December 13, 2006**. If this time frame is not acceptable, then please let me know immediately, and we can decide whether or not to extend your due date.

PLEASE EMAIL ME TO VERIFY RECEIPT OF THIS REQUEST

Question:

In your S2 response dated December 1, 2006, you provided a revised Design Control Activities Summary whereby you performed flexion/extension frictional torque analysis on the subject worst case 44 x66 mm bearing pair compared to the cleared 55x62mm ASR bearing pair (K040627). In your analysis, the data was analyzed after 90 cycles. Please explain the clinical relevance of testing and measuring the torque values after only 90 cycles.

Sincerely,

Julie B. Gantenberg
 Biomedical Engineer
 Orthopedic Joint Devices Branch
 U.S. Food and Drug Administration
 NW 240-276-3676 (tel) (formerly 301-594-2036)
 NW 240-276-3602 (fax) (formerly 301-594-2358)
julie.gantenberg@fda.hhs.gov

This e-mail message is intended for the exclusive use of the recipient(s) named above. It may contain information that is protected, privileged, or confidential, and

12/18/2006



TO: K062426
FROM: Kathy Harris
DATE: December 13, 2006
SUBJECT: DePuy Pinnacle® Metal-on-Metal Acetabular Cup Liners
K062426

I spoke with Julie Gantenberg concerning the response to her question of 12/8/06 regarding the reason for choosing 90 cycles. Ms. Gantenberg indicated that the response should include how many cycles that the predicate device was tested for. I indicated that we would have the response to her by close of business on December 13, 2006.

510(k): Premarket Notification

December 13, 2006

Food and Drug Administration
CDRH/ODE
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, MD 20850

Attn: Ms. Gantenberg

Re: S2 Request for Additional Information - K062426 DePuy Pinnacle Metal-on-Metal
Acetabular Cup Liners

Dear Ms. Gantenberg:

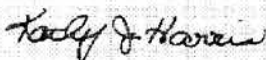
DePuy Orthopaedics, Inc. submits the enclosed documentation via email as an addendum to the DePuy Pinnacle Metal-on-Metal Acetabular Cup Liners K062426, currently under review by FDA. This submission is made to comply with the request for additional information made by e-mail on December 8, 2006.

Pursuant to 21 CFR 807.95(c) (3), DePuy considers our intent to market this device and this 510(k) submission to be confidential commercial information and requests that FDA treats it as such. DePuy has taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

DePuy Orthopaedics acknowledges that the introduction of this device into domestic commercial distribution will be contingent upon written clearance of the 510(k) by the Food and Drug Administration.

Thank you in advance for your consideration of our application. If there are any further questions regarding this submission, please feel free to contact Kathy Harris at (574) 372-7082 or email at kharris10@dpus.jnj.com.

Regards,



Kathy J. Harris
Director of Regulatory Affairs
DePuy Orthopaedics, Inc.



a Johnson & Johnson company
DePuy Orthopaedics, Inc.

PO Box 988
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988
USA

Tel: +1 (574) 287 8143

**Addendum II to DePuy Pinnacle Metal-On-Metal Acetabular Cup Liners 510(K),
K062426**

Request for Additional Information, December 8, 2006

Question:

In your S2 response dated December 1, 2006, you provided a revised Design Control Activities Summary whereby you performed flexion/extension frictional torque analysis on the subject worst case 44 x66 mm bearing pair compared to the cleared 55x62mm ASR bearing pair (K040627). In your analysis, the data was analyzed after 90 cycles. Please explain the clinical relevance of testing and measuring the torque values after only 90 cycles.

Response:

Testing was also completed to 90 gait cycles for the Predicate Device, the 55x62 ASR Modular Acetabular Cup System bearing pair (K040627). Data from the test on the Pinnacle Metal-on-Metal Acetabular Cup Liners (K062426), obtained from the University of Leeds testing lab, shows that there was no significant difference in the mean friction factor after 30 cycles, indicating that stabilization occurred around 30 cycles. 90 cycles was chosen as a standard analysis point since it is well after stabilization.

**Special 510(k)
REVIEW AND APPROVAL**

Final Draft of: Pinnacle Metal-On-Metal Acetabular Cup Liners

By: Anne Schuler 8-10-06

Extension: 7098

Reviewer	Signature	Date Reviewed
Becca Nofitz Project Engineer	<i>Becca Nofitz</i>	8/10/06
Paul Berman Product Director, Hips Marketing	<i>Paul Berman</i>	8/11/06
Paul Lewis Staff Engineer	<i>Paul Lewis</i>	8-14-06
John Emchmiser <i>EDMUND FRAZER</i> QA Process QE Manager	<i>Edmund M. Frazer</i>	16-08-06
Kathy Harris Director, Regulatory Affairs	<i>Kathy Harris</i>	Aug-16-06

Comments by Reviewer(s) and Signature(s):